

REAL WORLD TESTING PLAN

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”

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: Citiustech.Inc

Product Name(s): PERFORM+ Connect

Version Number(s): 22.01.02

Certified Health IT Product List (CHPL) ID(s): 15.04.04.2694.Perf.22.01.0.230426

Developer Real World Testing Plan Page URL: <https://www.citiustech.com/hubfs/citiustech-2024/products/perform/Real-World-Testing-Plan-2025-Perform-Connect-22-01-02.pdf>

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.¹

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.

Real World Testing Measurements The measurements for our real world testing plan are described below.

Measurement contains:

- *Associated ONC criteria*
- *Testing Methodology used*
- *Description of the measurement/metric*
- *Justification for the measurement/metric*
- *Expected outcomes in testing for the measurement/metric*
- *Care settings which are targeted*

All measurements were chosen to best evaluate compliance with the certification criteria and interoperability of exchanging electronic health information (EHI).

Testing Methodologies For each measurement, a testing methodology is used. For our test plan, we use the following methodologies.

Reporting: *This methodology uses the reporting capabilities of the product to examine functionality performed in the system. A typical example of this is the measure reporting done for the measure calculation. This methodology often provides historical measurement reports which can be accessed at different times of the year and evaluate interoperability of product functionality, and it can serve as a benchmark for evaluating real world testing over multiple time intervals. Compliance and/or Tool: This methodology uses inspection to evaluate if EHR is compliant to the ONC criteria requirements. It can be done through inspection testing or utilize various tools to measure or evaluate compliance and interoperability.*

Survey/Self-Test: *This methodology evaluates interoperability and compliance of PERFORM+ Connect module capabilities through feedback from users. Test patients will include data elements that are typically used in that provider setting in order to be representative of Real World use cases. ONC has recognized that self-testing can be a viable method for evaluation and compliance.*

STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) STANDARDS UPDATES

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 ID for each Health IT Module
- ✓ Date notification sent to ONC-ACB
- ✓ Date notification sent to customers
- ✓ Method used to demonstrate conformance with updated standard(s)
- ✓ Measurement(s)/metric(s) associated with Real World Testing

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|--|----------------|
| Standard (and version) | Not applicable |
| Updated certification criteria and associated product | Not applicable |
| Health IT Module CHPL ID | Not applicable |
| Date of ONC ACB notification | Not applicable |
| Date of customer notification | Not applicable |
| Conformance method and measurement/metric(s) | Not applicable |

MEASUREMENT(S)/METRIC(S) 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
- ✓ Justification for selected measurement/metric
- ✓ Care setting(s) that is addressed
- ✓ Expected outcomes

Description of Measurement/Metric

Describe the measurement(s)/metric(s) that will be used to support the overall approach to Real World Testing.

| Measurement/Metric | Description |
|----------------------------|---|
| Patient Engagement | The export files with single patient's or patient population's electronic health information were successfully created on using the PERFORM+ Connect product. |
| Patient Health Information | Patient will use the test page to query the API for: - A patient token to be used to query for additional data - Their test results and prescriptions |

| Criterion | Metric | Care setting | Justification and expected outcome |
|---|--|---|---|
| §170.315(b)(10) : Electronic Health Information export | An external system requests EHI for individual PERFORM+ Connect patients. A user exports the data and provides it to the requester. Key Metrics: 1 Request Volume: Number of individual EHI requests. 2 Response Time: Average time to fulfill requests. 3 EHI Completeness: Percentage of complete data exported. 4 User Efficiency: Number of steps to complete the export. 5 Auditability: Ability to track and audit the | Patient Engagement And Patient Health Information | Enable a user to timely create an export file(s) with all of a single patient's or patient population's electronic health information that can be stored at the time of certification by the product, of which the Health IT Module is a part. The export file(s) created must be electronic and in a computable format. The publicly accessible hyperlink of the export's format must be included with the exported file(s) Expected Outcome: We intended to enable a user to create an export file(s) with all of a single/multiple patient's electronic health information the health IT produces and electronically manages on that patient. |

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| | <p>process. 6 Error Rate: Percentage of failed export requests. Success Criteria:</p> <ul style="list-style-type: none"> • 95% of requests fulfilled within the specified time. • 99% data accuracy and completeness. • Export process completed in 5 steps or fewer. | | |
| §170.315 (g)(7): Application Access - Patient Selection | <ol style="list-style-type: none"> 1. Number of requests for a patient level token 2. Number of requests for a patient level token that provided provide a valid response. 3. Number of valid patient level tokens that provided a successful response for a data request | Patient Engagement And Patient Health Information | <p>All three metrics planned can be provided. As per §170.315(g)(7) Application access — patient selection, the PERFORM+ Connect must be able to receive a request with sufficient information to uniquely identify a patient and return an ID or other token that can be used by an application to subsequently execute requests for that patient's data.</p> <p>User is able to login to PERFORM+ Connect and select the patient record they are managing before a thirdparty patient facing app registered with PERFORM+ Connect is able to access the patient data using an access token provided by PERFORM+ Connect for the selected patient record.</p> <p>The reporting scripts accurately reports counts based on the captured metrics for the selected reporting period.</p> <p>Our expectation is that there will be moderate utilization by applications registered in PERFORM+ Connect for the FHIR API</p> |
| §170.315 (g)(10) Standardized API for patient and population services | <ol style="list-style-type: none"> 1) # of successful Vs total # of data requests for single patient tokens 2) # of successful Vs total # of data requests for multi-patient tokens 3) # of successful Vs total # of search requests 3) # of Applications | Patient Engagement And Patient Health Information | <p>All nine metrics planned can be provided.</p> <p>The captured metrics provide the numerator and denominator of specific aspects mandated by the Standardized API for patient and population services, thereby showing the utilization of the certified FHIR API.</p> |

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| | <p>registered</p> <p>4) # of successful Vs total # of refresh token requests</p> <p>5) # of successful Vs total # of access token requests based on a refresh token</p> <p>6) # of successful Vs total # of token revocation requests</p> <p>7) # of successful Vs total # of token introspection requests</p> <p>8) # of successful Vs total # of token requests for a public app</p> | | <p>The reporting scripts accurately report counts based on the captured metrics for the selected reporting period.</p> <p>We expect that there will be high utilization by applications registered in PERFORM+ Connect for the FHIR API.</p> |
|--|--|--|--|

Associated Certification Criteria

List certification criteria associated with the measurement/metric. If conformance to the criteria depends on any Relied Upon Software, this should be noted in your Real World Testing plan for any metrics that would involve use of that software in testing.

| Measurement/Metric | Associated Certification Criteria | Relied Upon Software (if applicable) |
|---|--|--------------------------------------|
| Patient Engagement And Patient Health Information | §170.315(b)(10): Electronic Health Information export | |
| | §170.315 (g)(7): Application Access - Patient Selection | |
| | §170.315 (g)(10): Standardized API for patient and population services | |

Justification for Selected Measurement/Metric

Provide an explanation for the measurement/metric selected to conduct Real World Testing.

| Measurement/Metric | Justification |
|---|---|
| Patient Engagement And Patient Health Information | <p>These criteria will be tested together.</p> <p>B10 - Enable a user to timely create an export file(s) with all of a single/multiple patient's or patient population's electronic health information that can be stored at the time of certification by the product, of which the Health IT Module is a part.</p> <p>G7 – The technology must be able to receive a request with sufficient information to uniquely identify a patient and return an ID or other token that can be used by an application to subsequently execute requests for that patient's data</p> |

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| | <p>G10 – The API must support API-enabled “read” services for single and multiple patients. “Read” services include those that allow authenticated and authorized third-party applications to view EHI through a secure API.</p> <p>We intend that the API must include accompanying documentation that contains, at a minimum: API syntax, function names, required and optional parameters and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns. The terms of use for the API must be provided, including, at a minimum, any associated developer policies and required developer agreements.</p> |
| | |

Care Setting(s)

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 |
|---|--|
| General Acute care and critical access hospital | The Certified Health IT Developer markets its Modules in Emergency department (ED)/ Inpatient settings only, so this is the only care setting in which Real World Testing is to occur. |
| Multi facility hospital system | The Certified Health IT Developer markets its Modules in Emergency department (ED)/ Inpatient settings only, so this is the only care setting in which Real World Testing is to occur. |

Expected Outcomes

Health IT developers should detail how the approaches chosen will successfully demonstrate that the certified health IT:

- 1) is compliant with the certification criteria, including the required technical standards and vocabulary codes sets;
- 2) is exchanging electronic health information (EHI) in the care and practice settings for which it is marketed for use; and/or,
- 3) EHI is received by and used in the certified health IT.

(from 85 FR 25766)

Not all of the expected outcomes listed above will be applicable to every certified Health IT Module, and health IT developers may add an additional description of how their measurement approach best addresses the ongoing interoperability functionality of their product(s). Health IT developers could also detail outcomes that should not result from their measurement approach if that better describes their efforts.

Within this section, health IT developers should also describe how the specific data collected from their Real World Testing measures demonstrate expected results. Expected outcomes and specific measures do not necessarily have to include performance targets or benchmarks, but health IT developers should provide context for why specific measures were selected and how the metrics demonstrate individual criterion functionality, EHI exchange, and/or use of EHI within certified health IT, as appropriate.

| Measurement/Metric | Expected Outcomes |
|---|--|
| Patient Engagement And Patient Health Information | 170.315(b)(10): <ul style="list-style-type: none"> • Includes all the EHI for a patient population as described in § 170.315(b)(10); • Is electronic and in a computable format; and • Includes a publicly accessible hyperlink of the export’s format. |

| | |
|--|---|
| | <p>§170.315 (g)(7): The technology must be able to receive a request with sufficient information to uniquely identify a patient and return an ID or other token that can be used by an application to subsequently execute requests for that patient's data.</p> <p>§170.315 (g)(10): The API must support API-enabled "read" services for single and multiple patients. "Read" services include those that allow authenticated and authorized third-party applications to view EHI through a secure API.</p> |
| | |

SCHEDULE OF KEY MILESTONES

Include steps within the Real World Testing plan that establish milestones within the process. Include details on how and when the developer will implement measures and collect data. Key milestones should be relevant and directly related to expected outcomes discussed in the next section.

For each key milestone, describe when Real World Testing will begin in specific care settings and the date/timeframe during which data will be collected.

| Key Milestone | Care Setting | Date/Timeframe |
|---|---|------------------------|
| Development of software and/or SQL queries to be used for data analysis | Patient Engagement And Patient Health Information | March, 2025 |
| Begin collection of information as laid out by plan | Patient Engagement And Patient Health Information | June, 2025 |
| Analysis and report creation | Patient Engagement And Patient Health Information | January-February, 2026 |

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.

Authorized Representative Name: Madhu Madhanan

Authorized Representative Email: madhumadhanan@citiustech.com

Authorized Representative Phone: +1(877)248-4871

Authorized Representative Signature:

Date:

26-Nov-24



ⁱ Certified health IT continues to be compliant with the certification criteria, including the required technical standards and vocabulary codes sets; certified health IT is exchanging EHI in the care and practice settings for which it is marketed for use; and EHI is received by and used in the certified health IT. (85 FR 25766)

ⁱⁱ <https://www.federalregister.gov/d/2020-07419/p-3582>