ONC Health IT Certification Program

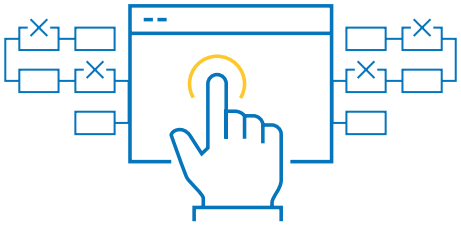
The Office of the National Coordinator for Health Information Technology

Real World Testing

What It Means for Health IT Developers

A Practical Overview of Real World Testing Requirements

This factsheet describes Real World Testing requirements for Health IT Developers participating in the ONC Health IT Certification Program (Program). This resource will assist the Health IT Developer community in understanding how the requirements outlined in the ONC 21st Century Cures Act Final Rule apply to them, and provide a practical overview of the Real World Testing Condition and Maintenance of Certification requirements.



After reviewing this factsheet, developers will know:

- What is Real World Testing
- Who is required to conduct Real World Testing
- Deadlines for Real World Testing
- How Real World Testing impacts Certified Health IT Modules
- Ongoing responsibilities for Certified Health IT Developers
- Where to find additional Real World Testing information

This document touches on aspects of the ONC-Authorized Certification Body (ONC-ACB) role, however, its primary purpose is to **assist developers with Certified Health IT Modules in understanding what is required to meet the Real World Testing Condition and Maintenance of Certification requirements.**

What is Real World Testing?

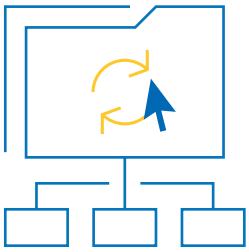
Real World Testing is a process by which Health IT Developers demonstrate interoperability and functionality of their Certified Health IT in real world settings and scenarios, rather than in a controlled test environment with an ONC-Authorized Testing Lab (ONC-ATL). Real World Testing verifies that deployed Certified Health IT continues to perform as intended by conducting and measuring observations of interoperability and data exchange. These observations are described in a public and transparent way through Real World Testing plans and reported as Real World Testing results.

Health IT Developers have flexibility in the way they choose to develop their Real World Testing plans and are encouraged to consider metrics that could highlight the quality of their Certified Health IT products for end users.

Interoperability is, with respect to health information technology, such health information technology that—

- Allows for complete access, exchange, and use of all electronically accessible health information, ***and***
- Enables the secure exchange and use of electronic health information (EHI) without special effort on the part of the user.

(from 85 FR 25940)



SVAP

Real World Testing also enables Health IT Developers to participate in the Standards Version Advancement Process (SVAP), allowing them to demonstrate conformance to National Coordinator-approved newer versions of adopted standards.

Who Is Required to Conduct Real World Testing?

Real World Testing is a Condition of Certification and includes ongoing Maintenance of Certification requirements in the Program. As part of the Condition of Certification, Health IT Developers with one or more Health IT Module(s) certified to any of the certification criteria outlined in §170.405(a) of the ONC Cures Act Final Rule must successfully test the real world use of those Health IT Module(s).

Table 1 provides a snapshot of the certification criteria applicable to Real World Testing. Certified Health IT Developers should review this table to determine if any of the applicable criteria fall within the scope of their Certified Health IT Module(s)' certification. Regardless of whether one, some, or all of the certification criteria listed below are included within the certification scope, Real World Testing is required.

In order to maintain their certification(s), ongoing Maintenance of Certification requirements specify that Health IT Developers must develop a plan and submit a results report for these same criteria on an annual cycle for each of the setting types in which their Certified Health IT Module(s) are marketed.

Successful Real World Testing means . . .

- 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.

(from 85 FR 25766)

Click on any of the links below for the Test Method and Certification Companion Guide (CCG) for each criterion.

Table 1
Applicable Real World Testing Certification Criteria

Care Coordination

§ 170.315(b)(1) Transitions of care

§ 170.315(b)(2) Clinical information reconciliation and incorporation

§ 170.315(b)(3) Electronic prescribing

§ 170.315(b)(6) Data export

§ 170.315(b)(7) Security tags - summary of care - send

§ 170.315(b)(8) Security tags - summary of care - receive

§ 170.315(b)(9) Care plan

§ 170.315(b)(10) Electronic Health Information export

★★★ Clinical Quality Measures

§ 170.315(c)(1)—record and export

§ 170.315(c)(2)—import and calculate

§ 170.315(c)(3)—report

Patient Engagement

§ 170.315(e)(1) View, download, and transmit to 3rd party

Electronic Exchange

§ 170.315(h)(1) Direct Project

§ 170.315(h)(2) Direct Project, Edge Protocol, and XDR/XDM

Public Health

§ 170.315(f)(1) Transmission to immunization registries

§ 170.315(f)(2) Transmission to public health agencies — syndromic surveillance

§ 170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results

§ 170.315(f)(4) Transmission to cancer registries

§ 170.315(f)(5) Transmission to public health agencies — electronic case reporting

§ 170.315(f)(6) Transmission to public health agencies — antimicrobial use and resistance reporting

§ 170.315(f)(7) Transmission to public health agencies — health care surveys

Application Programming Interfaces

§ 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

§ 170.315(g)(10) Standardized API for patient and population services

Real World Testing Process

The components of Real World Testing consist of three main activities.

Real World Testing occurs on a yearly cycle, but planning, conducting, and reporting Real World Testing for each given year means that a developer's Real World Testing activities from different years can overlap.

For example, the Real World Testing plan for calendar year 2022 is due in 2021, but results are not reported until 2023. In the meantime, another Real World Testing plan for calendar year 2023 would be due in 2022—before the results are reported for the calendar year 2022 Real World Testing plan.

Elements of the Real World Testing Plan

Elements of the Real World Testing plan are outlined in §170.405(b)(1)(iii) of the ONC Cures Act Final Rule. Each of the elements that are required to be included in the Real World Testing plan are explained in more detail below. These elements are designed to guide Health IT Developers in formulating their Real World Testing plans and demonstrating that their Certified Health IT is functioning as certified when implemented in the setting types it is marketed.

The plan must address the following elements for **each** certification criterion identified in Table 1 applicable to the Health IT Module's scope of certification:

- Testing method(s)/methodology(ies) that will be used to demonstrate real world interoperability and conformance to the full scope of the certification criterion's requirements, including scenario- and use case-focused testing;
- Care setting(s) that will be tested for real world interoperability and an explanation for the Health IT Developer's choice of care setting(s) to test;
- Descriptions of how the developer will test and demonstrate conformance to all requirements of the criterion using all versions of the adopted standard to which each Health IT Module was certified as of August 31 of the year in which the plan is due, including for any standards and implementation specifications that the developer has chosen to certify to National Coordinator-approved new versions of the adopted standard;
- Schedule of key Real World Testing milestones;
- Description of the expected outcomes of Real World Testing;
- Measurement/ metric (at least one) associated with the Real World Testing; and
- Justification for the Health IT Developer's Real World Testing approach.

Designing a Real World Testing Plan

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. The following sections provide additional considerations to assist developers in developing their own innovative and pragmatic approaches to conducting Real World Testing.

Determine Health IT Modules to Include

Real World Testing plans are intended to describe measurement approaches for the year immediately following the plan's submission. The plan should address any Health IT Modules certified by or before August 31 of the year in which the plan is submitted.

For example:
You are a Health IT Developer with two Certified Health IT Modules. Health IT Module #1 includes within its scope applicable Real World Testing certification criteria that completed certification in June 2021. Health IT Module #2 includes within its scope a different subset of applicable Real World Testing certification criteria, but was not certified until October of 2021. Your Real World Testing plan due by December 2021 will include only Health IT Module #1 for Real World Testing in calendar year 2022. This plan will be available on the Certified Health IT Product List (CHPL) by December 15, 2021. Because Health IT Module #2 was not certified as of August 31, 2021, it is not subject to Real World Testing requirements in the 2022 calendar year.

Health IT Module #2 would be included in the following year's Real World Testing plan for calendar year 2023 Real World Testing, which would be submitted by December 2022.

Determine Test Method(s)/Methodologies to Include

Developers must describe the test methods/ methodologies they plan to use in their individual Real World Testing. Real World Testing assesses Certified Health IT functionality used by customers of the developer post-certification. Developers should determine the best process and procedures for working with their customers to observe their Health IT Module's functionality in a production environment. Health IT Developers have the flexibility to identify and test against measures they believe are most appropriate to provide transparency on how they will assess interoperability capabilities within the care settings and workflows where their Certified Health IT Modules are used.

Here are some factors to consider when determining method(s)/methodologies:

- Size of the organizations that production systems support
- Type(s) of organizations and setting(s)
- Number of patient records and users
- System components and integrations
- Volume and types of data exchange in planning for Real World Testing

Because these factors vary from developer to developer, ONC has determined the developer is best suited to establish their own method(s)/methodologies for working with their customers to conduct Real World Testing. A Health IT Developer's approach to conducting Real World Testing should reflect these and other relevant factors that support the goal of demonstrating certified capabilities in real world scenarios.

Identify Partners in Each Care Setting Marketed

Developers must consider all setting types in which their product is marketed when determining their testing approach. Settings or health care provider types are not excluded from Real World Testing requirements based on eligibility or ineligibility for any particular Federal health care program or initiative.

Even Health IT Modules not yet deployed are still required to be considered in a Real World Testing plan. If a Health IT Developer does not have customers or has not deployed their Certified Health IT Module(s) at the time the Real World Testing plan is due, the Health IT Developer should address its prospective testing plans for the coming year.

While Health IT Developers are not required to test their Certified Health IT in each and every setting in which it is marketed for use, 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. Developers should address their choice of care and/or practice settings to test and provide a justification for the chosen approach.

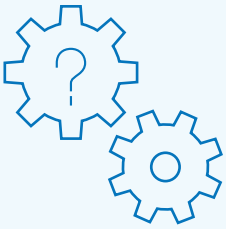
- Health IT Developers should describe the association with each Health IT Module's real world performance in the types of settings it is marketed.
- A Real World Testing plan is not required for each individual product or each individual care setting location.
- Health IT Developers may bundle products 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.
- Health IT Developers should construct real world scenarios or use cases that test more than one care setting applicable to the Health IT Module.

Establish a Schedule and Identify Key Milestones

Health IT Developers will include in their plans a timeline for conducting certain steps within their Real World Testing to establish milestones within the process. Milestones should include details on how and when the developer will implement measures and collect data. The plan should describe when certain measures within their chosen methods/methodologies will be implemented over the course of the applicable calendar year. Key milestones should be relevant and directly related to expected outcomes discussed in the next section.

Describe Expected Outcomes

Health IT Developers should detail how the approaches chosen will produce outcomes that reflect successful Real World Testing. Expected outcomes should provide transparency into what current and potential customers will know about the Certified Health IT Module(s) and its effectiveness in demonstrating interoperability when tested in the real world.



Expected outcomes could also reflect what should not be a result of a given action. Health IT Developers are encouraged to target outcomes that are measurable and indicate the level at which its Certified Health IT Module(s) are providing optimal user experience for its customers and other interested stakeholders.

Identify At Least One Measure

As mentioned in the previous section, Real World Testing should result in outcomes that clearly demonstrate how successful a Certified Health IT Module functions when deployed in a production environment. Each plan must include at least one measurement/metric that addresses each applicable certification criteria in the Health IT Module's scope of certification. Developers with Health IT Modules certified to multiple criteria should expect that they would incorporate more than one measurement/metric.

Because the applicable criteria are specific to data exchange and interoperability, developers should avoid measurement/metrics that indicate pass/fail or yes/no results, especially where those measures would not demonstrate ongoing interoperability or functionality per se.

The purpose of Real World Testing is to demonstrate that Health IT Modules continue to perform in conformance to their certification as they are deployed in production. Thus, real patient data and real production environments should be first considered when developing Real World Testing plans.

Although it is not specifically prohibited, developers are discouraged from using open-source test platforms or test platforms specific to their products as part of the Real World Testing process. Test tools and platforms deviate from the underlying goal of Real World Testing being conducted in and specific to the intended use cases and setting types in which the Certified Health IT is marketed.

Provide Justification for Approach

Health IT Developers must describe how the measurements/metrics they select reflect each of the required elements for Real World Testing. 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.

Submitting a Real World Test Plan

Real World Testing plans must be publicly available on the CHPL by December 15th of each year. However, ONC-ACBs may set deadlines to submit plans earlier in order to allow sufficient time to review the plans for completeness and make them publicly accessible. Plans must be made accessible via a URL hosted by Health IT Developers. Health IT Developers should be sure to contact their ONC-ACB for details about plan submission deadlines and other procedures for maintaining their Real World Testing plan URL on CHPL.

Reporting Results of Real World Testing

After submitting their Real World Test plan, Health IT Developers will gather data to represent how their products operate in the real world and submit these results to their ONC-ACB. The Real World Testing results report must address each element that is required for the Real World Testing plan for each Health IT Module with applicable criteria within its scope. A Health IT Developer's results report should reflect the approach and measures they submitted in their initial Real World Testing plan.

If during the course of their Real World Testing a Health IT Developer determines the approaches they established in their plan do not effectively demonstrate interoperability, they may adjust their methods/methodologies and report this adjustment in their results report. A new plan is not required. The Health IT Developer should submit the data derived from its original approaches with a statement indicating that a revised approach was established. The results report should clearly indicate the adjustments made, when they were made, and how the results reflect the new approach.

If a Health IT Developer discovers a non-conformity during the course of its Real World Testing, they must report it to their ONC-ACB within 30 days. The ONC-ACB will inform the Health IT Developer of processes for resolving the non-conformity.

Real World Testing results must be publicly available on the CHPL by March 15th of each year. Similar to the Real World Testing plan deadline, ONC-ACBs will determine a date by which the results report must be submitted in order for it to be made publicly available on CHPL. The results report should be made accessible via a URL hosted by Health IT Developers. Health IT Developers should contact their ONC-ACB for details about results submission deadlines.

Updates to Certifcation Criteria

The ONC Cures Act Final Rule requires Health IT Developers to update their Certified Health IT Modules to new standards for specific certification criteria. The Final Rule also provides additional flexibility for voluntary updates to National Coordinator-approved newer versions through the new Standards Version Advancement Process (SVAP). Both required and voluntary standards updates must be addressed in Real World Testing plans and results. 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. The following sections discuss the required updates and timeline for Health IT Developers to complete them.

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.

Standards Version Advancement Process (SVAP) and Real World Testing

The SVAP allows Health IT Developers to update their Certified Health IT Modules to use more advanced versions of standards and implementation specifications than the version(s) incorporated by reference in the regulation for the certification criteria. This flexibility is voluntary and only available for National Coordinator-approved newer versions of adopted standards.

Health IT Developers demonstrate conformance to the standards they have opted to use through the Real World Testing process. As a Maintenance of Certification requirement, a developer that chooses to pursue such updates must include each Certified Health IT Module updated to newer version(s) of any standards(s) in their next Real World Testing plan and test each Module the following calendar year for conformance to all applicable criteria within its scope, including the newer versions of standards.

USCDI Updates for C-CDA

The United States Core Data for Interoperability (USCDI) is a standardized set of health Data Classes and constituent Data Elements required to support nationwide electronic health information exchange. Health IT Developers are required to update their Certified Health IT to support the USCDI v1 for specific formerly Common Clinical Data Set (CCDS)-dependent 2015 Edition certification criteria.

Any Health IT Developer with Health IT Modules certified to the criteria listed below must update their Certified Health IT to be compliant with the revised versions of these criteria and provide its customers with the updated Certified Health IT by December 31, 2022.

- § 170.315(b)(1) Transitions of care;
- § 170.315(b)(2) Clinical information reconciliation and incorporation;
- § 170.315(e)(1) View, download, and transmit to 3rd party;
- § 170.315(f)(5) Transmission to public health agencies—electronic case reporting;
- § 170.315(g)(6) Consolidated CDA creation performance; and/or
- § 170.315(g)(9) Application access—all data request

For more information about USCDI v1, visit ONC's website.

C-CDA Companion Guide Updates

ONC has adopted the Consolidated Clinical Document Architecture (C–CDA) Companion Guide to align with our goal to increase the use of consistent implementation of standards among Health IT Developers and improve interoperability. Any Health IT Developer with Health IT Modules certified to the below certification criteria must update their Certified Health IT to be compliant with the revised versions of these criteria by May 2, 2022.

- § 170.315(b)(1) Transitions of care;
- § 170.315(b)(2) Clinical information reconciliation and incorporation;
- § 170.315(b)(9) Care plan;
- § 170.315(e)(1) View, download, and transmit to 3rd party;
- § 170.315(g)(6) Consolidated CDA creation performance; and/or
- § 170.315(g)(9) Application access—all data request

Electronic prescribing

The National Council for Prescription Drug Programs (NCPDP) SCRIPT 10.6 standard was replaced in the ONC Cures Act Final Rule to Version 2017071. Any Health IT Developer with Health IT Modules certified to the §170.315(b)(3) Electronic prescribing criteria must update their Certified Health IT to be compliant with the revised version of this criterion by December 31, 2022.

Security tags

Implementing security tags enables providers to more effectively share patient records with sensitive information, thereby protecting patient privacy while still delivering actionable clinical content. Any Health IT Developer with Health IT Modules certified to § 170.315(b)(7) Security tags - summary of care - send and/or § 170.315(b)(8) Security tags - summary of care - receive must update their Certified Health IT to be compliant with the revised versions of the criteria by December 31, 2022.

ASTM updates

Since adopting the Auditable events and tamper-resistance (§ 170.315(d)(2)), Audit Reports (§ 170.315(d)(3)), and Auditing Actions on health information (§ 170.315(d)(10)) criteria in the 2015 Edition, there has been an update to the American Society for Testing and Materials (ASTM) standard. Given the older version has been deprecated, we have updated these criteria with the latest standard, ASTM E2147—18 in § 170.210(h). Any Health IT Developer with Health IT Modules certified to §170.315(d)(2), (d)(3), and/or (d)(10), must update their Certified Health IT to be compliant with the revised versions of the criteria by December 31, 2022.

Clinical Quality Measures – Report

ONC removed the Health Level 7 (HL7R) Quality Reporting Document Architecture (QRDA) standard requirements in the 2015 Edition ‘‘Clinical Quality Measures—report’’ criterion in § 170.315(c)(3) and, in their place, requires Health IT Modules to support the CMS QRDA Implementation Guide(IGs). Any Health IT Developer with Health IT Modules certified to §170.315(c)(3) must update their certified health IT to be compliant with the revised versions of this criterion and provide its customers of the previously certified health IT with the updated certified health IT by December 31, 2022.

Real World Testing is an opportunity for Health IT Developers to determine their own testing approaches and measures to provide transparency into how effectively their certified Health IT Module(s)' meets interoperability and data exchange functionality requirements. It also provides Health IT Developers the opportunity to advance to newer versions of standards and demonstrate that their certified Health IT Module(s) continues to meet certification requirements. ONC encourages Health IT Developers to come up with approaches and measures that provide their users and the public with transparency into functionality that accurately and effectively reflects how the certified Health IT Module(s) functions when deployed.

Additional Resources

ONC 21st Century Cures Act Final Rule
https://www.healthit.gov/curesrule/

ONC 21st Century Cures Act Final Rule Resources
https://www.healthit.gov/curesrule/resources/fact-sheets

2015 Edition Cures Update Certification Criteria
https://www.healthit.gov/topic/certification-ehrs/2015-edition-cures-update-test-method

Certified Health IT Product List (CHPL)
https://chpl.healthit.gov/#/resources/overview

Standards Version Advancement Process (SVAP)
https://www.healthit.gov/isa/standards-version-advancement-process

ONC Certification Program Resources
https://www.healthit.gov/topic/certification-ehrs/certification-resources

Conditions and Maintenance of Certification
https://www.healthit.gov/topic/certification-ehrs/conditions-maintenance-certification