

ONC HEALTH IT CERTIFICATION PROGRAM

REAL WORLD TESTING RESOURCE GUIDE

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Introduction

BACKGROUND AND PURPOSE

Under the ONC Health IT Certification Program (Certification Program), Certified 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 Certified Health IT developers' responsibilities for conducting Real World Testing, to identify topics and specific elements required by Real World Testing, and to assist Certified Health IT developers with developing their Real World Testing plans.

Disclaimer

While every effort has been made to ensure the accuracy of restatements of 45 CFR Part 170, this guide is not a legal document. The official requirements are contained in the relevant laws and regulations. This resource should be read and understood in conjunction with the following companion resources.

COMPANION RESOURCES AND OTHER RELEVANT MATERIALS

This resource should be read and understood in conjunction with the following companion resources, which describe in detail many of the Certification Program requirements referenced in this resource.

- [Real World Testing–What It Means for Health IT Developers – Fact Sheet](#)
- [Real World Testing Certification Companion Guide](#)
- [Real World Testing Plan Template](#)
- [Real World Testing Results Report Template](#)

Certified 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”
- Interim Final Rule with Comment Period, Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency, [85 FR 70064](#) (November 4, 2021) (**IFC**)

TERMINOLOGY

To make this resource more accessible, some plain language terms are used for certain regulatory concepts. The use of these terms is strictly for convenience and does not impose any new requirements or alter the interpretation of existing requirements under the Certification Program. When encountering any of the following terms noted in the table below in this resource, the reader should substitute the following definitions:

Table 1: Terminology Used in This Resource

Term	Definition
compliance	With respect to a requirement of the Certification Program, conformity with such requirement.
developer	A person or entity that submits health IT for certification under the Certification Program and/or is responsible for maintaining a certification issued to health IT under the Certification Program.
non-conformity	The failure of certified health IT or of a Certified Health IT developer to conform to a requirement of the Certification Program.
product	A Health IT Module or other health IT that has been issued a certification or has been submitted for certification under the Certification Program (as the context requires).
production environment	Any real world setting (such as a hospital or doctor’s office) in which the capabilities of certified health IT are implemented or used.
Certification Program	The ONC Health IT Certification Program.
required capability or certified capability	A capability or other aspect of health IT that is required by one or more certification criteria to which the technology is certified, typically comprising one or more required outcomes (as defined below).
required outcome	Any characteristic that a product must possess or any outcome it must enable to support a required capability (as defined above).
technology	A “product” (as defined above).
testing	The process of evaluating a product’s performance under simulated and/or controlled conditions, including but not limited to testing conducted prior to certification under the supervision of an ONC-Authorized Testing Lab (ONC-ATL) in accordance with approved test procedures, testing tools, and, where applicable, test data.

TEXT BOXES

To assist developers in preparing their Real World Testing plans, a number of gray shaded text boxes appear throughout this document. The text boxes provide a roadmap and checklist for developers as they develop their Real World Testing plans. However, developers need to thoroughly review all parts of this resource guide and other materials cross-referenced herein and address all required aspects of Real World Testing in their Real World Testing plans.

HOW TO USE THIS GUIDE

ONC established in [45 CFR 170.405\(b\)\(1\)\(iii\)](#) the topics and considerations every developer must address in their required Real World Testing plan. ONC does not specify how developers must address these required elements in order to provide the developers with the flexibility to develop and implement successful Real World Testing plans that will best balance burden and value for the customers of each of their products. This resource will assist developers in organizing these required elements according to their product(s) unique customer base, workflows, and setting type(s) in which they’re marketed—without defining the

actual approaches they will take to conduct Real World Testing. ONC also has incorporated a limited number of scenarios and use cases for illustrative purposes only. These scenarios are based on public comment on the ONC Cures Act Final Rule, inquiries received in ONC's Health IT Feedback and Inquiry Portal, and public listening sessions held with stakeholders. The scenarios and other information presented in this guide may not be universally applicable to every developer or their individual circumstances, nor is it intended to be. The information is meant to be illustrative in nature only. Real World Testing as a process allows maximum flexibility for developers to devise their own testing methodologies and approaches to publicly report on the interoperability of their certified products in real-world environments. Based on the questions and feedback received, we have developed this resource to provide direction for developers to consider how the required elements may be collated in a way that eliminates redundancy, increases productivity, and maximizes on the time and efforts dedicated to conducting Real World Testing.

Real World Testing Process

WHAT IS REAL WORLD TESTING?

Real World Testing is a Condition of Certification and includes ongoing Maintenance of Certification requirements in the Certification Program. As a Condition of Certification, 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 Modules. Real World Testing is a process by which Certified Health IT developers demonstrate in a public and transparent way interoperability and functionality of their certified health IT in production settings and scenarios, rather than in a controlled test environment with an ONC-Authorized Testing Lab (ONC-ATL). Real World Testing is also how Certified Health IT developers who use newer versions of specific standards approved by ONC demonstrate conformance to these newer standards.

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 initial Real World Testing plans and reported in subsequent Real World Testing results. Certified Health IT developers have flexibility to develop their Real World Testing plans and are encouraged to consider metrics that could highlight the quality of their certified health IT products. Developers with products certified under the Certification Program must submit a Real World Testing plan (45 CFR 170.405(b)(1)) that describes in detail how the developer will implement all required aspects of Real World Testing.

A Certified Health IT developer's demonstration of interoperability-focused functionality is critical to advancing transparency on the Health IT Modules' performance and provides information that could help users decide which certified health IT to acquire. As defined in § 170.102 of the ONC Cures Act Final Rule, "Interoperability is, with respect to health information technology, such health information technology that—

- 1) Enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user;
- 2) Allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable state or federal law; and
- 3) Does not constitute information blocking as defined in § 171.103."

([85 FR 25940](#))

SUBMISSION REQUIREMENTS AND DEADLINE

Deadlines

All certifications issued as of August 31 must be included and addressed in the Real World Testing plan applicable to the next calendar year.

The **plan** for the upcoming year must be made public via a hyperlink on the Certified Health IT Product List (CHPL) by December 15.

Results for the plan must be made public via a hyperlink on the CHPL no later than March 15 following the measurement year.

The ONC-Authorized Certification Body (ONC-ACB) is required to conduct a completeness review prior to publishing the plan hyperlink on the CHPL by December 15 of each year and the results report hyperlink by March 15 of each year. In order for plans and results reports to be submitted to ONC and made publicly available by the required deadlines, the ONC-ACB will require the developer to submit their plan and results report in advance of the respective deadline. Certified Health IT developers should familiarize themselves with their ONC-ACB's deadline for submission and work with their ONC-ACB to ensure their plan and results report are accessible via CHPL by the deadlines above.

If a developer fails to meet the ONC-ACB requirement for submission, the ONC-ACB will issue a non-conformity consistent with its processes and procedures for addressing a customer failing to meet any other requirement. The ONC-ACB will notify ONC if there are concerns regarding a Certified Health IT developer not meeting requirements that will impact the ONC-ACB's ability to meet the deadlines for when Real World Testing plans and results must be made public.

DESIGNING REAL WORLD TESTING PLANS

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

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](#)

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\(g\)\(9\) Application access— all data request](#)
- [§ 170.315\(g\)\(10\) Standardized API for patient and population services](#)

Electronic Exchange

- [§ 170.315\(h\)\(1\) Direct Project](#)
- [§ 170.315\(h\)\(2\) Direct Project, Edge Protocol, and XDR/XDM](#)

In order to maintain their certification, ongoing Maintenance of Certification requirements specify that Certified Health IT developers must develop a plan and submit a results report for these same criteria on an annual cycle for the setting types in which their Certified Health IT Modules are marketed. Developers with products certified under the Certification Program must submit a Real World Testing plan that describes in detail how the developer will implement all required aspects of Real World Testing. Their Real World Testing results report should speak to what was outlined in their previous year's plan.

MODIFYING REAL WORLD TESTING APPROACHES

ONC anticipates that throughout a developer's Real World Testing activities there will be instances where the developer may find a need to modify their testing methodologies or approaches that were originally laid

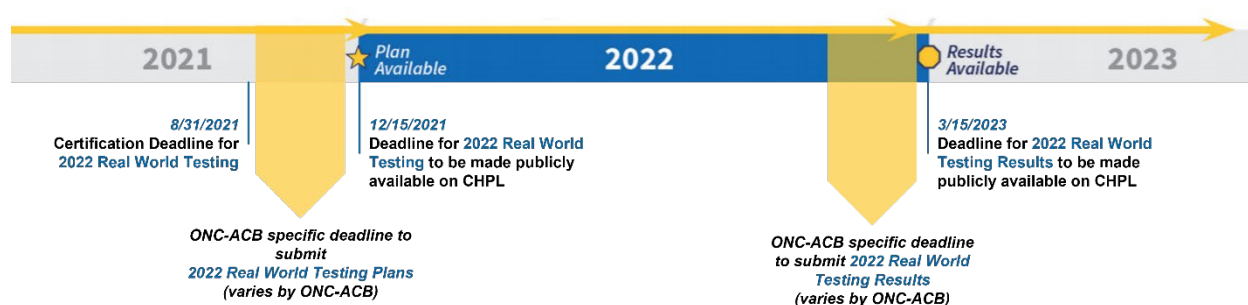
out in their plan(s) to address unexpected changes during the testing period. The developer is not prohibited from adjusting their approaches following the submission of their original plans.

To promote public transparency, ONC recommends that developers do not update the plans themselves but include any changes to their Real World Testing approach in their results report. If a developer adjusts their Real World Testing approaches, ONC expects that the Real World Testing results report will include a description of these types of changes, the reasons for the changes, and how intended outcomes were more efficiently met as a result. The ONC-ACB may have additional requirements for handling adjustments to Real World Testing approaches.

Real World Testing Cycle and Overlap

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.

Image 1: Submission Deadlines



REAL WORLD TESTING TEMPLATES

Real World Testing was designed specifically to allow Certified Health IT developers flexibility in the measures they can implement, and ONC encourages developers to create measures for their specific health IT and their particular customer base that demonstrate both interoperability and compliance with required standards. However, ONC has developed **optional** Real World Testing templates to assist Certified Health IT developers in organizing the required information that must be submitted for each element in their Real World Testing plan and results report. While the use of the templates is voluntary, developers may find it useful in preparing their Real World Testing plans and results reports. The [templates](#) will also assist developers with ensuring they have developed complete Real World Testing plans and results reports that sufficiently addresses all the required elements.

COMPLETENESS REVIEW

Prior to making them publicly available on the CHPL, ONC-ACBs will assess Real World Testing plans and results reports for completeness. Certified Health IT developers should thoroughly review all ONC Real World Testing resources, including this guide, to ensure they have appropriately addressed all aspects of their Real World Testing requirements. Likewise, when reporting on the previous year’s Real World Testing

results, developers' results reports should directly address what was stated in their plan, present the data that was collected to support the outcomes, and clearly articulate how each element was addressed to demonstrate successful Real World Testing.

CERTIFIED HEALTH IT PRODUCT LIST (CHPL) AND REAL WORLD TESTING

To be open and transparent to the public, developers must provide a hyperlink to their Real World Testing plans and results reports on an annual basis to be published with the applicable Health IT Module(s) on the CHPL. Because Real World Testing is an annual requirement for Certified Health IT developers, developers should use a single URL from which all current and previous years' Real World Testing plans and results reports can be accessed. It is the Certified Health IT developer's responsibility to organize the plans and results reports hosted at the link, indicating the relevant year for the plans and results reports and keeping them up-to-date as needed in order to promote full public transparency on their Real World testing approaches.

One Plan/Results Link as a Landing Page

The CHPL only allows for publication of one Real World Testing plan link and one Real World Testing results report link. To ensure continued access to current and previous years' plans and results reports, developers should provide a single link on the CHPL to a landing page to host all materials for public access. This will mean that multiple years of Real World Testing plans and results reports should be accessible from the link provided. We note that developers are responsible for ensuring these links continue to work and are publicly accessible following the submission and publication to the CHPL.

Image 2: Public Availability of Real World Testing Plans/Results



Real World Testing Plan – General Information

DUTY TO CONDUCT REAL WORLD TESTING

A developer has a duty to conduct Real World Testing of their certified health IT. This duty consists of devising a plan, gathering data, and reporting the data in a results report to execute on their Real World Testing responsibilities, requiring developers to proactively plan and seek out information about the performance of their certified health IT products and capabilities related to interoperability and data exchange. The way developers market and make such products and capabilities available to customers and users must be considered in their overall approach to Real World Testing.

Overall Approach to Real World Testing

Real World Testing plans should describe clearly and in significant detail the developer's overall approach to conducting Real World Testing. The plan should demonstrate the developer's thorough understanding of its Real World Testing responsibilities by comprehensively addressing all required elements described in this document, and detailing sound approaches and methodologies for performing all applicable aspects of Real World Testing under the Certification Program.

Certified Health IT developers must submit one plan for each year of Real World Testing. If adjustments to approaches are made throughout Real World Testing, the developer should reflect these adjustments in their Real World Testing results report. Real World Testing results report should include a description of these types of changes, the reasons for them, and how intended outcomes were more efficiently met as a result. ONC has included in the optional results report template suggested ways to included these changes in Real World Testing results reports.

REAL WORLD TESTING REOCCURRENCE AND OVERLAP

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. Real World Testing plans are intended to describe measurement approaches for the year immediately following the plan's submission. Results reports should reflect the data collected through the previous year of Real World Testing.

This process is required on an ongoing, yearly basis for all Health IT Modules obtaining certification with applicable certification criteria. Developers may include in their Real World Testing plan for the following calendar year any Health IT Modules certified after August 31, but this is not required. Developers that chose to include updates made after the August 31 deadline in their testing plan for the following calendar year must also include those modules as part of requirements in their next cycle of Real World Testing. At a minimum, Certified Health IT developers must include in their Real World Testing plan for the following calendar year all health IT certified as of August 31 regardless of whether the health IT was included in their Real World Testing in a previous year.

INHERITED CERTIFIED STATUS

Inherited Certified Status (ICS) allows developers to update their product to a newer version and get it certified without additional testing when the ONC-ACB determines that the updates do not adversely impact

the product's ability to meet certification requirements. A new listing is created on the CHPL for the newer version, changing the certification date, although it's the same product with the same functionality. ONC is aware that some developers update their certified health IT leveraging ICS, then withdraw the previous listing.

When a developer leverages ICS after the August 31st deadline for Real World Testing eligibility and gets a newer version of a Real World Testing-eligible product certified, then withdraws the previous listing, the newer version of that product inherits the Real World Testing requirement along with its certification. Developers must ensure that they meet Real World Testing requirements for all eligible products as of August 31st of each year. Including the updated, newer ICS version(s) of a product required for Real World Testing will ensure that the developer does not inadvertently fail to meet the Real World Testing results reporting requirement for a given Real World Testing cycle. Thus, developers that choose to update via ICS should apply the newer version(s) to their Real World Testing plan and include in their results report details on how they managed the various ICS versions of their product required for Real World Testing.

Real World Testing Plan Elements

There are specific elements that developers must include in their Real World Testing plan for it to be considered complete and accepted by an ONC-Authorized Certification Body (ONC-ACB).

- 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 required capabilities
- Care setting(s) that will be tested for real world interoperability and an explanation for the Certified 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, including any Relied Upon Software needed to demonstrate conformance
- 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
- Justification for the Certified Health IT developer's Real World Testing approach

Justification for Real World Testing Approach

Each Real World Testing plan must include an overall description and justification for the approach taken in the plan. The justification should describe how the developer determined the appropriate conformity assessment techniques and methodologies employed, including the factors that the developer considered in determining how it plans to measure success in its Real World Testing. The justification is an overarching statement that provides the rationale behind the approach the developer has chosen to take for its Real World Testing plan.

EMPLOYING APPROPRIATE REAL WORLD TESTING METHODOLOGIES

Developers must determine the best process and procedures for working with their customers to observe their Health IT Module's functionality in a production environment and describe the testing and/or measurement methodologies they plan to use in their individual Real World Testing. Certified Health IT developers may develop a single plan that addresses more than one certification criterion and multiple Health IT Modules.

Some factors to consider when determining method(s)/methodology(ies):

- 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
- Certification criteria measured, either individually or concurrently
- Health IT Modules addressed, either individually or concurrently
- Use of Inherited Certified Status Flexibility

One Plan or Many?

Developers have flexibility to structure their Real World Testing plans in whatever way they think will best convey information. A single Real World Testing plan can address more than one certification criterion and multiple Health IT Modules.

TESTING ENVIRONMENTS

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 environments. 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 opensource 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. However, data from test tools and platforms could be considered in conjunction with data from Health IT Modules deployed in

production environments if there are circumstances in which the production environment will not yield sufficient measures to demonstrate interoperability and functionality (i.e., there is low adoption of a capability).

Standards Updates

Standards Updates

Real World Testing plans must include all certified health IT updated to newer versions of standards prior to August 31st of the year in which the updates were made.

UPDATES TO CERTIFIED HEALTH IT MODULES

The ONC Cures Act Final Rule included several requirements for developers to update their Certified Health IT Modules to newer standards for individual certification criteria. These updates were required by December 31, 2022. It also provided flexibility for voluntary updates to newer standards made through the Standards Version Advancement Process (SVAP). Whenever a developer updates a Certified Health IT Module, they should report such updates to their ONC-ACB and these updates must be addressed in Real World Testing. Once these standards updates are complete, developers must include the updated certification criteria in subsequent Real World Testing plans. 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. Developers are accountable for providing transparency into their certified health IT functionality after updating to newer standards.

Any developer with certified health IT subject to the required standards updates listed below is required to account for the functionality of their updated certified health IT in their Real World Testing activities. For more information about the updates listed below, please review the [Cures Update Overview Fact Sheet](#).

- United States Core Data Set (USCDI) Updates
- C-CDA Companion Guide Updates
- Electronic Prescribing Updates
- Security Tags
- ASTM Updates
- Clinical Quality Measures (CQM) – Report

For CQMs, because the Centers for Medicare & Medicaid Services (CMS) updates the associated standards annually, developers generally update their products outside of the Certification Program to comply with the CMS reporting requirements. The Standards Version Advancement Process' (SVAP's) annual advancement of standards versions adopted in the Certification Program provides flexibility to better support developer adherence to these standards. We note that, because of different CMS reporting and publishing timelines, the SVAP advancement of new versions of the CMS QRDA Implementation Guides will always lag approximately six months behind CMS publication.

STANDARDS VERSION ADVANCEMENT PROCESS (SVAP)

The Standards Version Advancement Process (SVAP) permits developers to voluntarily update health IT products certified under the Certification Program to newer versions of adopted standards as part of Real World Testing.

Using SVAP, Certified Health IT developers are permitted to voluntarily use a newer approved version of a standard than is adopted in regulation. Currently, this flexibility is limited to standards that are adopted in the certification criteria required to meet the Real World Testing Condition of Certification, which include:

- [“Transitions of care”](#) (§ 170.315(b)(1));
- [“Clinical information reconciliation and incorporation”](#) (§ 170.315(b)(2));
- [“Electronic prescribing”](#) (§ 170.315(b)(3));
- [“Data export”](#) (§ 170.315(b)(6));
- [“Security tags – summary of care – send”](#) (§ 170.315(b)(7));
- [“Security tags – summary of care – receive”](#) (§ 170.315(b)(8));
- [“Care plan”](#) (§ 170.315(b)(9));
- [“Electronic Health Information export”](#) (§ 170.315(b)(10));
- [“CQMs – record and export”](#) (§ 170.315(c)(1));
- [“CQMs – import and calculate”](#) (§ 170.315(c)(2));
- [“CQMs – report”](#) (§ 170.315(c)(3));
- [“View, download, and transmit to 3rd party”](#) (§ 170.315(e)(1));
- [“Transmission to immunization registries”](#) (§ 170.315(f)(1));
- [“Transmission to public health agencies – syndromic surveillance”](#) (§ 170.315(f)(2));
- [“Transmission to public health agencies – reportable laboratory tests and value/results”](#) (§ 170.315(f)(3));
- [“Transmission to cancer registries”](#) (§ 170.315(f)(4));
- [“Transmission to public health agencies – electronic case reporting”](#) (§ 170.315(f)(5));
- [“Transmission to public health agencies – antimicrobial use and resistance reporting”](#) (§ 170.315(f)(6));
- [“Transmission to public health agencies – health care surveys”](#) (§ 170.315(f)(7));
- [“Application access – patient selection”](#) (§ 170.315(g)(7));
- [“Application access—all data request”](#) (§ 170.315(g)(9)); and
- [“Standardized API for patient and population services”](#) (§ 170.315(g)(10))
- [“Direct Project”](#) (§ 170.315(h)(1))
- [“Direct Project, Edge Protocol and XDR/XDM”](#) (§ 170.315(h)(2))

For approved newer versions of standards, developers leveraging the SVAP flexibility can do so on initial certification of their Health IT Module(s) or for their existing certified Health IT Module(s). Developers will

need to ensure the updates to the newer approved standard versions are effectively implemented and also adhere to all applicable Certification Program requirements.

Developers taking advantage of the SVAP flexibility must also ensure that their Real World Testing plans and results reports of the Certified Health IT Modules address these updated standards. Additionally, developers updating their already Certified Health IT Modules are required to provide advance notice to their clients and ONC-ACB before adopting a newer approved version of a standard.

Working with industry stakeholders, ONC has developed a collaborative public comment process to identify newer versions of standards that are ready for use in the Certification Program. For additional information on the annual process; including the list of standards and versions eligible for consideration and requirements for their advance notice, please visit the [SVAP Process Page](#).

How to Take Advantage of SVAP Flexibility

For existing certifications to applicable certification criteria, Certified Health IT developers are required to provide advance notice to their clients and ONC-ACB before adopting the new standards. When updating their certified health IT to newer standards approved by ONC, developers are not required to re-test with their ONC-ACB. Rather, they must account for these updates in their Real World Testing plan and report on their Real World Testing results.

SVAP can be implemented by developers in a few simple steps:

- Provide advance notice to all affected customers and their ONC-ACB to:
 - express intent to update to the more advanced version of the standard;
 - outline expectations for how the update will affect interoperability of each affected Health IT Module; and
 - indicate whether they intend to continue to support the certificate(s) for the existing Certified Health IT Module(s) version.
- Successfully demonstrate conformance with approved more recent versions of the standard(s) included in each updated certification criterion.
- Maintain the updated Certified Health IT Module(s) in full conformance with all applicable Certification Program requirements.

For new certifications to applicable certification criteria, an SVAP notice is not required. The developer demonstrates conformity with the ONC-ATL under lab testing or directly to the ONC-ACB depending on the certification criterion. For certification to criteria with available SVAP-approved standards, developers can choose to certify using either to the newer SVAP-approved standard or to the standard referenced in regulation.

Certification to Criterion	Health IT Developer Leveraging SVAP
Existing Certification	<ul style="list-style-type: none"> • Provide advance notice to affected customers and ONC-ACB. • Attest conformance directly to the ONC-ACB for their Certified Health IT Module updating to the approved SVAP version of the adopted standard. • Address updated SVAP standard in Real World Testing plans and results, in addition to adhering to all other applicable Program requirements.
New Certification	<ul style="list-style-type: none"> • Demonstrate conformance to the ONC-ATL, or ONC-ACB as applicable, of their Health IT Module <ol style="list-style-type: none"> a. Directly to the approved SVAP version of the adopted standard, or b. If applicable to the criterion, both the approved SVAP version and the standard version incorporated by reference. • Address updated SVAP standard in Real World Testing plans and results, in addition to adhering to all other applicable Program requirements.

SVAP and Real World Testing

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 plan should, at a minimum, detail the following:

- What certification criteria in which product(s) has been updated
- CHPL ID for each Health IT Module
- Product ID for each product
- Method used for standard update (e.g., SVAP)
- Date notification sent to ONC-ACB
- Date notification sent to customers
- Certification criteria affected by the update
- Measure used to demonstrate conformance with updated standard

Measurements/Metrics

MEASUREMENT/METRIC ASSOCIATED WITH REAL WORLD TESTING

Real World Testing is a process by which developers demonstrate in a public and transparent way interoperability and functionality of their certified health IT in production settings and scenarios, rather than in a controlled test environment. While Certified Health IT developers have flexibility in the measures or metrics they select for their Real World Testing, they should keep in mind the following:

- Every Real World Testing plan must have a minimum of one measure.

- Each applicable certification criterion in the Health IT Module’s scope of certification must be addressed in a measurement or metric in the developer’s Real World Testing.
- Developers with multiple Certified Health IT Modules and/or products certified to multiple certification criteria will likely incorporate more than one measure in order to adequately address Real World Testing.
- Each type of clinical setting in which their certified health IT is marketed must be addressed in Real World Testing, but each clinical setting does not necessarily have to be measured or represented in every measure or metric that is part of the Real World Testing plan.
- Measurements and metrics can be combined in many different ways to yield results for Real World Testing. One measure could potentially address multiple criteria and multiple care settings. It is up to the developer to describe how the measure would do so.
- Measures and metrics should demonstrate ongoing interoperability and functionality relative to the certification criteria. ONC encourages developers to avoid single test metrics or measures that establish product functionality only at a single point in time. For example, a metric that only demonstrates a Certified Health IT Module completing a function once or on a specific date does not demonstrate ongoing interoperability or functionality. However, such a metric could be part of a larger measure that demonstrates continued functionality across a span of time.
- Where possible, measures should include a defined denominator to serve as a baseline for understanding the context in which the testing occurred. For example, 100 successful CCD downloads may look different for two different products if one does not understand how many download attempts occurred in testing.

Factors that may weigh in favor of choosing the metric(s)	Factors that may weigh against choosing the metric(s)
Type of data	
<ul style="list-style-type: none"> ✓ Real patient data ✓ Rate of success/failure ✓ Number of errors compared to successes over time 	<ul style="list-style-type: none"> ✗ Yes/no ✗ Pass/fail ✗ Use of test tool as proxy measure
Collection method	
<ul style="list-style-type: none"> ✓ Data derived from networks that developers participate in ✓ Data derived from use of test tools 	<ul style="list-style-type: none"> ✗ Surveillance results indicating conformity/non-conformity ✗ Single instance of demonstrating interoperability or data exchange

When choosing measures, there are some specific scenarios that ONC would like to present for developers to consider.

Relied Upon or Third Party Software

Relied upon software is typically third party software that is not developed by the Certified Health IT developer presenting its health IT for testing and certification. When a developer relies upon software to demonstrate compliance with a certification criterion, such relied upon software must be included in the scope of the certification issued to the Health IT Module.

The objective of Real World Testing is to verify the extent to which certified health IT deployed in production environments continues to demonstrate conformance to the full scope of applicable certification criteria and functions with the intended use cases as part of the overall maintenance of a Health IT Module's certification. This would include any relied upon software used to demonstrate conformity with its initial certification. Therefore, health IT developers must include and address relied upon software as part of their Real World Testing.

Relied Upon Software

If a health IT developer uses any relied upon software to demonstrate conformity for a specific certification criterion, they must include and address relied upon software as part of their Real World Testing.

Resellers of Certified Products

Developers that work with business partners/distributors and permit them to sell their (unmodified) certified health IT under their own brand/name/label should consider how they will communicate Real World Testing requirements for their re-marketed product(s) to their business partners/distributors. ONC does not specify whether the reseller or the original developer is required to fulfill Real World Testing requirements for a product that is being marketed by resellers. However, Real World Testing, and associated requirements, is required for all Certified Health IT Product List (CHPL) listings with an active certification to any of the certification criteria specified in 45 CFR 170.405(a). These criteria are listed in section II.B of this guide for ease of reference.

ONC permits the inheritance of Real World Testing plans and results by developers' authorized resellers. ONC notes that with respect to the types of settings required to be addressed by a given developer's plan, the original developer may or may not market in the same types of settings as the reseller. It is the reseller's responsibility to ensure the types of settings in which they resell the certified health IT are addressed in Real World Testing and either conduct Real World Testing themselves or provide their ONC-ACB with evidence (i.e. plan(s) and results report(s)) that the original developer has already conducted Real World Testing and addressed all setting types in which the product is being marketed.

ONC believes that the developers are best positioned to determine how they will ensure all setting types are included in Real World Testing activities, including those they may not market in, but their reseller(s) does. Therefore, ONC has not defined in regulation how developers should handle reseller responsibilities for Real World Testing. ONC does not believe that additional specification is necessary because each developer is well situated to know in what types of settings the developer (or its authorized resellers) has marketed, is marketing, or intends to market its Health IT Modules (85 FR 25771). ONC-ACBs may have requirements for how they will track and monitor health IT developers' processes for managing resellers' adherence to Real World Testing requirements similar to how ONC-ACBs monitor other reporting

requirements for resellers of certified health IT. ONC reiterates that Real World Testing for certified health IT must address all types of settings of care—so if the original developer doesn't address the setting type(s) in which the reseller resells, then that would not meet the requirement for Real World Testing.

Cloud-based Products

Because the purpose of Real World Testing is to test health IT products as they are deployed in production, developers of health IT products deployed through the cloud who offer their products for multiple types of clinical settings will be required to test the same capability for those different types of settings, even if it uses a single instance of the deployed capability to serve all those types of settings (85 FR 25768).

The finalized Real World Testing Condition and Maintenance of Certification requirements include testing each criterion listed in § 170.405(a) to which any Health IT Module(s) within the product are certified, and testing in each type of setting to which it is marketed. To satisfy these Condition and Maintenance of Certification requirements as finalized, a single testing plan, protocol, or approach must address all the types of settings in which the product, with all its included Health IT Module(s), is marketed and do so with traceability to each Health IT Module of its real world performance in each type of setting for which it is marketed (85 FR 25771).

Non-deployed and/or Low Use Capabilities

ONC is aware of instances where a developer may market certified health IT that includes Health IT Modules or other capabilities that can be deployed on a modular basis so that some Module(s) may be deployed to customers and in use while others are not deployed or are not used. For example, ONC established 2015 Edition certification criteria that requires certified health IT to be able to send and receive health information in accordance with specified standards such as § 170.315(h) transport methods and other protocols (e.g., (h)(1)/(h)(2)). In this example, a HISP vendor could have no customers using the SMTP-based edge protocol version of Direct. For such a scenario, the ONC-ACB must still account for that capability for accurate representation on the CHPL as it is required by the developer's certification and for Real World Testing. Thus, the developer is still required to address this capability in their Real World Testing plan and, if the capability is deployed to customers, their Real World Testing activities regardless of how often the deployed capability is actually used by those customers. If the developer has not yet deployed a particular certified Health IT Module to any real world users when the annual Real World Testing results are due for that module, the developer would need to report as such to meet the Real World Testing requirement.

The policy includes substantial flexibility for developers to assess how to meet the Real World Testing Condition and Maintenance of Certification requirements in a way that appropriately minimizes burden on the current users of their certified health IT and offers the developer a substantial opportunity to design Real World Testing approaches that fully optimize the value of the Real World Testing activities and results to current and prospective customers. This includes, though is not limited to, flexibility for the developer to 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. Real World Testing also provides developers the opportunity to identify, potentially in partnership with their customers, the real-life scenarios, use cases, and workflows applicable to the customer's day-to-day use of the Health IT Module(s) to meet their interoperability needs in their production environments.

ADDRESSING REAL WORLD TESTING ELEMENTS WITHIN CHOSEN MEASURES

Developers must describe approaches for measuring the success of their Real World Testing. For each measure chosen, a developer must include the following in their Real World Testing plans:

- Description of the measurement/metric
- Associated certification criteria (and Relied Upon Software needed for associated criteria, if applicable)
- Justification for selected measurement/metric
- Care setting(s) addressed
- Expected outcomes

Description of the Measure

Certified Health IT developers must describe their measures, the metric or data collected, and how the measure supports the demonstration of successful Real World Testing. When thinking about measures, developers should consider how data, metrics, and measurements will work together to produce evidence of successful interoperability and functionality in production environments. Full descriptions should make it clear to anyone who accesses the Real World Testing plan what data is collected for the measure, how that data is collected, the denominator or baseline for the measure to be considered against (if applicable) (e.g., number of attempts, size of testing group, etc.), the time period of measurement, and how the measure is intended to demonstrate functionality of the associated certification criteria.

Associated Certification Criteria

Certified Health IT developers should clearly articulate the certification criteria addressed in each measure. Additionally, if a single measure is being used to demonstrate interoperability and functionality for multiple Certified Health IT Modules, then the Real World Testing Plan must clearly identify which Modules and certification criteria are associated with the measure. In addition, ONC recommends developers provide an inventory or crosswalk of measures, certification criteria, and associated Modules as part of their Real World Testing plans and results report so that ONC-ACBs can more easily conduct completeness reviews.

Justification for the Measure

Certified Health IT developers must provide a rationale or justification for how the measure will successfully demonstrate interoperability and functionality for the certification criteria, associated Certified Health IT Modules, and/or indicated care setting(s). Developers should be able to describe how the specific data, metrics, and measurements collected as part of a measure produce evidence of successful interoperability and functionality in production environments. The justification should reflect how the measure is relevant to the developer's overall strategy for meeting the Real World Testing Condition and Maintenance of Certification requirements.

Care Settings Addressed

Certified Health IT developers must consider all setting types in which their product is marketed when determining their testing approach. While 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. For example, a

developer may market its product to urology practices. In this example, the policy does not require that Real World Testing be conducted in every urology practice into which the product is deployed, but at least one urology setting must be tested to address this setting type during Real World Testing.

Developers should address their choice of care and/or practice settings for each measure. While every care setting does not need to be addressed for each measure, all care setting types in which the product is marketed and all certification criteria within the scope of the product's certification must be fully addressed in the Real World Testing plan as a whole. Settings or healthcare provider types are not excluded from Real World Testing requirements based on eligibility or ineligibility for any particular federal healthcare program or initiative.

ONC does not specifically define or limit the care settings and leaves it to the developer to determine the types of care setting(s) in which their certified health IT is marketed and used.

As an example, developers can consider categories, including but not limited to:

- those used in the Promoting Interoperability Program;
- long-term and post-acute care;
- pediatrics;
- behavioral health; and/or
- small, rural, and underserved settings

There may be some care settings for which a Health IT Module is marketed but not yet deployed or in use. Even Health IT Modules not yet deployed are still required to be included in a Real World Testing plan. If a 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 developer should address its prospective testing plans for the coming year.

Expected Outcomes

Certified 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.

[\(85 FR 25766\)](#)

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

Within this section, developers should also describe how the specific data collected from their Real World Testing measures would demonstrate expected results. Expected outcomes and specific measures do not necessarily have to include performance targets or benchmarks, but 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.

Reporting Non-conformities

§ 170.405(b)(2)(i) requires that if in the course of conducting Real World Testing the developer discovers one or more non-conformities with the full scope of any certification criterion under the Certification Program, the developer must report that non-conformity to the ONC-ACB within 30 days.

A Certified Health IT Module that fails to successfully demonstrate full compliance of certification capabilities during one or more of their Real World Testing demonstrations should be treated as any other observation of a failure to meet specific Certification Program requirements. The ONC-ACB would be expected to implement its procedures for investigating self-reported non-conformities in these instances and may decide to conduct surveillance. If the developer disputes that their product is the cause of the failure during Real World Testing, this would be discovered during the ONC-ACB investigation. A dispute could arise from errors caused by user error, network failure, or non-compliance on the part of the receiving system. This could also be expanded to include situations where Developer A submits their results and implicates a receiving system (Developer B) for non-compliance, while Developer B's test results indicate compliance with all interoperability requirements and no failures during their own testing. Some factors that the ONC-ACB would consider include, but are not limited to, the potential that Developer A is correct and if so whether Developer B also identified the non-compliance of Developer B's product. If Developer B's own Real World Testing did not identify the non-compliance in their product, the ONC-ACB would consider why not. It is possible for any developer's Real World Testing plan and approach to inadvertently miss some faults or errors in the deployed product, though this could in some circumstances indicate weaknesses in the developer's plan that they should strive to address in their future Real World Testing plans. However, if Developer B had awareness or indication of the non-conformity and deliberately adjusted their Real World Testing approach or documentation to avoid reporting it, they would in addition to the underlying non-compliance of their product also be out of compliance with the requirement to disclose non-conformities found during their Real World Testing (§ 170.405(b)(2)(i)).

Schedule of Key Milestones

Developers must 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 dates and timeframes indicating specific actions within their Real World Testing for when and how the developer will implement measures and collect data. The plan should describe when and how certain measures within their chosen methods/methodologies will be implemented over the course of the applicable calendar year. Some examples of Real World Testing milestones include but are not limited to:

- Initial development of the Real World Testing plan;
- Development of candidate list of providers to assist with the Real World Testing;
- Development of software, which could be used to gather data for analysis;

- Finalization of the Real World Testing plan, and submission to ONC-ACB per ONC-ACB instruction;
- Collection of information as laid out by the plan for the period;
- Validation of expected outcomes;
- Completion of test suites;
- Cycle of testing begin and end,
- Completion of testing phases;
- End of Real World Testing period/final collection of all data for analysis; and
- Analysis and report creation.

DESIGNING A REAL WORLD TESTING RESULTS REPORT

Certified Health IT developers must submit results from their Real World Testing. The results submitted should be based on and directly related to the Real World Testing plan submitted for the immediately preceding calendar year. Developers will gather data to represent how their product operates in the real world and submit these results to their ONC-ACB. Like the Real World Testing plan deadline, the ONC-ACB will determine a date by which the results report must be submitted in order for it to be made publicly available on CHPL no later than March 15 of each calendar year (see Section II.C. for submission deadlines). The results report will be made accessible via a URL hosted by Certified Health IT developers. Because results reporting is an annual requirement, developers should use a single landing page link from which all current and previous years' Real World Testing results reports can be accessed. Certified Health IT developers should contact their ONC-ACB for details about results report submission deadlines and other procedures for maintaining their Real World Testing plan URL on the CHPL.

The Real World Testing results report must address each required element in the Real World Testing plan for each Health IT Module with applicable criteria within its scope. ONC has developed an **optional** Real World Testing template to assist Certified Health IT developers in organizing the required information that must be submitted for each element in their Real World Testing results report. A developer's results report should demonstrate traceability to what they stated in their plan. In designing their results report(s), developers should consider how they structured the plan and align their results report to ensure traceability between the two documents. For example, if a developer submitted one plan for all 10 eligible products, they may want to consider submitting one results report for the same 10 products. Alternatively, if they submitted a separate plan for each eligible product, they may want to consider submitting a separate results report for each product as well.

Real World Testing Results Elements

There are specific elements that developers must include in their Real World Testing results report for it to be considered complete and accepted by an ONC-Authorized Certification Body (ONC-ACB).

- Any changes to the Real World Testing plan that occurred during the execution of the plan, why those changes occurred and the impact on the intended outcomes of the testing (if applicable)
 - These changes may include any products that were withdrawn since the submission of the Real World Testing plan
- Testing method(s)/methodology(ies) that were used to demonstrate real world interoperability and conformance to the full scope of the certification criterion's required capabilities
- Care setting(s) that were tested for real world interoperability
- Voluntary updates to the standards and implementation specifications approved through SVAP (if applicable)
- List of key Real World Testing milestones
- Description of the outcomes of Real World Testing, including any challenges encountered
- Measurement/metric (at least one) associated with the Real World Testing

Changes to Real World Testing Approach

Certified Health IT developers may discover during Real World Testing that methods/methodologies, measurements/metrics, and other approaches selected do not produce the anticipated expected outcomes. Issues may arise during the collection of data that require a developer to adjust their strategies. If during their Real World Testing a developer determines that the approaches they established in their plan are not the most appropriate for reaching the expected outcomes, they may adjust their methods/methodologies and report this adjustment in their results report. A new plan is not required. The developer should submit the data derived from its original approaches with a statement indicating that in retrospect a more appropriate approach was established. If a developer changed its plan during the course of conducting Real World Testing, they should specify in their Real World Testing results report what changes they applied to their approach, the reason for the change, and how the change in approach impacted results. The results report should clearly indicate the adjustments made, when they were made, and how the results reflect the new approaches.

Inclusion of Withdrawn Products

In some cases, a developer may withdraw a product that was eligible for Real World Testing after the submission of a plan but before the submission of the results report. If this occurs, the developer should include in their Real World Testing results report information about the product(s) that was withdrawn, including: product name(s), version number(s), CHPL ID(s), date(s) withdrawn, and whether any data from that product will be included in the results report.

Developers do not have to include results from withdrawn products in their reports but have the opportunity to do so if it supports their demonstration of real world interoperability and usability. For example, if the developer has multiple versions of the same product under ICS and withdrew earlier versions of that

product, they may still want to include results from testing that version if it helps demonstrate the product's conformance in the real world.

APPENDIX: Real World Testing Scenarios and Use Case Examples

This Appendix presents two hypothetical examples of how a Certified Health IT developer could approach selecting measures that address all the required Real World Testing elements. Scenario 1 includes two use cases describing how a Certified Health IT developer might address a single certification criterion. Scenario 2 describes how a Certified Health IT developer might address several certification criteria.

Please note that these scenarios are for illustrative purposes only. The information presented in this Appendix is intended to provide stakeholders with examples only and will not be applicable to any specific developer or Certified Health IT Module(s). The information is educational and not meant to prescribe or dictate the structure or contents of Real World Testing plans beyond what is required in § 170.405.

Real World Testing as a process allows maximum flexibility for developers to devise their own testing methodologies and approaches to publicly report on the interoperability and functionality of their certified products in production environments. ONC expects developers to create their own approaches to measurement and testing and not adopt the exact approaches described in the use cases below.

Real World Testing is a process by which Certified 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. Although some Real World Testing measures could utilize data collected by providers, the regulatory responsibility for conducting Real World Testing is on the Certified Health IT developer.

REAL WORLD TESTING: SCENARIO 1 – SINGLE CRITERION

Scenario 1 provides an example of a Real World Testing plan for a single certification criterion, “Standardized application programming interface (API) for patient and population services,” (§ 170.315(g)(10)). To cover the entire criterion, two use cases are presented for this plan. Use Case 1 demonstrates a stand-alone application (“Standalone-launch”) for a single patient, while Use Case 2 demonstrates an internal EHR application (“EHR-launch”) for population services that is deployed as part of the Certified Health IT Module.

Scenario 1, Use Case 1 Overview: Patient Services. To test the real world interoperability and conformance of its certified API technology, a Certified Health IT developer, who markets to providers in pediatric settings, works with a third-party developer of a smartphone application called “Child Wellness App”. The goal of the application is to provide parents with a synopsis of their well-child’s care, follow-up requirements based upon the visit, results, and/or relevant education materials. The Certified Health IT developer will test the ability of its certified API technology to manage multiple applications’ requests for patient data using the single patient services requirements at § 170.315(g)(10).

Scenario 1, Use Case 2 Overview: Population Services. In addition to supporting the use of the Child Wellness App, the Certified Health IT developer supports an application meant to allow providers to manage their patient population. The “Child Wellness Population App” enables providers to see health trends across patients in a pediatric setting and identify opportunities for patient educational information. The application allows a provider to query their population based on relevant USCDI data and then return the relevant patients and their medical records, which can be further analyzed using the application functions. The Certified Health IT developer will test the ability of its certified API technology to manage multiple applications’ bulk data access requests for patient data using the population services requirements at § 170.315(g)(10).

Sample Real World Testing Plan Elements

The remaining sections of this document detail the overall approach a fictional Certified Health IT developer is taking for their Real World Testing. The information below includes Real World Testing elements as Certified Health IT developers should/could express them in their Real World Testing plans.

Justification for Real World Testing Approach

The Child Wellness App only supports the retrieval of patient information for a single patient at a time, so all user scenarios for this app focus on the single patient data requirements of the “Standardized API for patient and population services,” (§ 170.315(g)(10)) certification criterion. On the other hand, the Child Wellness Population App focuses on the population services requirements in the certification criterion. The goal of this approach is to demonstrate that both the interoperability and conformance capabilities of the certified API technology are consistent with the requirements of the § 170.315(g)(10) certification criterion. This will be done through the test scenarios included in the plan, as demonstrated by use of the two applications and a reliance on the Certified Health IT developer’s views of multiple applications’ interactions with the certified API technology.

Standards Updates (SVAP and USCDI)

Standard (and version)	All standards versions are those specified in USCDI v1.
Date of ONC-ACB notification (SVAP or USCDI)	Not applicable
Date of customer notification (SVAP only)	Not applicable
USCDI-updated criteria	None

Care Setting(s)

Pediatric Care Setting: The Certified Health IT developer markets its Modules in pediatric care settings only, so this is the only care setting in which Real World Testing will to occur.

Overall Expected Outcome(s)

- Real World Testing will show that the Child Wellness App provided each use/user of requested data, with less than 1 percent errors.

- Real World Testing will demonstrate that the Health IT Module is conformant to § 170.315(g)(10) for the “Standardized API for Patient and Population Services” certification criterion.
- Real World Testing will demonstrate that the Health IT Module is interoperable as specified by § 170.315(g)(10) using FHIR® APIs to relay USCDI data elements to a client and FHIR® Bulk Data Access (Group Export) to retrieve the USCDI data classes/elements (or a sub-set depending on the Child Wellness Population App function) for a specified set of patients.
- Real World Testing will demonstrate that the Certified Health IT developer’s certified API technology can manage multiple patient services and population services applications at a time.

Schedule of Key Milestones

Key Milestone	Date/Timeframe
Release of documentation for the Real World Testing to be provided to authorized representatives and providers running the Child Wellness App. This includes surveys, specific instructions on what to look for, how to record issues encountered, and Customer Agreements.	December 1, 2021
Begin collection of information as laid out by the plan.	January 1, 2022
Meet with previously identified providers and authorized representatives to ensure that Real World Testing protocols are effective.	February 2022
Follow-up with providers and authorized representatives to understand any issues arising with the data collection.	Quarterly, 2022
Data collection and review.	Quarterly, 2022
End of Real World Testing period/final collection of all data for analysis.	January 2023
Analysis and report creation.	January 15, 2023
Submit Real World Testing report to ACB (per their instructions)	February 1, 2023

Measures Used

The following outlines the measures that have been identified to best demonstrate conformance to the § 170.315(g)(10) “Standardized API for patient and population services” certification criterion across the single patient and multiple patient use cases.

Use Case 1 (Patient Services) Metrics: As part of the Real World Testing requirements for “Standardized API for patient and population services” (§ 170.315(g)(10)) (patient services only), the Certified Health IT developer has identified the following metrics for their testing plan:

Measure 1: Conformance to “Standardized API for patient and population services” (§ 170.315(g)(10)) (patient services only). This measure will test the conformance of the certified API technology using the Child Wellness App. The associated certification criterion in the pediatric care setting is:

Certification Criteria	Requirement
§ 170.315(g)(10) Standardized API for patient and population services (patient services only)	(i) Data response
	(ii) Supported search operations
	(iii) Application registration (standalone launch)
	(iv) Secure connection (provider specific)
	(v) Authentication and authorization

- Justification: Since the Child Wellness App only provides access to specific patient data through the FHIR® interfaces, this will provide a metric on the use of FHIR® APIs to access patient data. Additionally, credentialing requirements will be tested indirectly, as only authorized users will have access to the child’s data. This will be further verified through the review of the log files.
- Test methodology: Log files obtained during Real World Testing will be de-identified and used for analysis in several areas to validate the proper operation of § 170.315(g)(10) “Standardized API for patient and population services.” For FHIR® APIs, this includes proper credentialing and validation that all required USCDI data elements are supported.
- Expected outcome(s): It is expected that the Child Wellness App will be conformant to § 170.315(g)(10) with less than 1 percent error rate experienced by users.

Measure 2: Management of Multiple Applications. This measure will review the number of applications registered to certified API technology and associated performance across multiple applications. Performance will pertain to application data access, refresh tokens, and revocations that occur at the patient’s authorization. The associated certification criterion in the pediatric care setting is:

Certification Criteria	Requirement
§ 170.315(g)(10) Standardized API for patient and population services (patient services only)	(i) Data response
	(ii) Supported search operations
	(v)(A)(2) Subsequent connections
	(vi) Patient authorization revocation
	(vii) Token introspection

- Justification: The Certified Health IT developer’s certified API technology should accommodate the full range of § 170.315(g)(10) functionality for multiple applications designed for single patient services. This measure would look at the performance of the certified API technology to manage multiple applications at once.

- Test methodology: Cases will be reviewed using the log file history to ensure multiple applications registered to the certified API technology enable data access, support refresh tokens for at least 90-day intervals, and enable revocations to occur at the patient’s authorization. Log files obtained during Real World Testing will be de-identified and used for analysis in several areas to validate the proper operation of “Standardized API for patient and population services” as specified in § 170.315(g)(10)(i); (ii); (v)(A)(2); (vi); and (vii) and associated implementation guides, including validation that all required USCDI data elements are supported.
- Expected outcome(s): It is expected that data access issues are rare and that the functionalities identified in the above criteria perform without errors. Error rates will be tracked across these functions as part of a base line for the initial testing year.

Use Case 2 (Population Services) Metrics: As part of the Real World Testing requirements for “Standardized API for patient and population services” (§ 170.315(g)(10)) (population services only), the Certified Health IT developer has identified the following metrics for their plan, working in conjunction with the Child Wellness Population App developer.

Measure 1: Completeness of Response. This measure will test providers’ usage of the Child Wellness Population App, assessing completeness of responses relative to requests across provider-users. The associated certification criterion in the pediatric care setting is:

Certification Criteria	Requirement
§ 170.315(g)(10) Standardized API for patient and population services (population services only)	(i) Data response
	(ii) Supported search operations
	(iii) Application registration (EHR launch for FHIR® Bulk Data Access and Backend Services)
	(iv) Secure connection (provider specific)
	(v) Authentication and authorization

- Justification: Since the Child Wellness Population App only provides access to specific patient data through the FHIR® interfaces, this will provide a metric on the use of FHIR® population services aspect of (g)(10) to access patient data. Additionally, credentialing requirements will indirectly be tested, as only authorized users will have access to the child’s data. This will be further verified through the review of the log files.

- **Test methodology:** Logs will be reviewed to determine how often providers use the Child Wellness Population App. Embedded in the log data (for the purposes of Real World Testing) will be the length of time used to run the queries and the data fields used for the query. Log files obtained during Real World Testing will be de-identified and used for analysis in several areas to validate the proper operation of FHIR® APIs and population services as specified in § 170.315(g)(10). For FHIR® Bulk Data Access, this includes proper credentialing and expected behavior of FHIR® group-export. This test methodology will primarily test the conformance of the implementation. Due to the client/server nature of the FHIR® API implementation, it will also demonstrate the interoperability of the implementation.
- **Expected outcome(s):** Based on the log files, the following information can be derived: access to the sets of USCDI data elements used for the query/return, the total number of FHIR® Bulk Data Access requests made, and the duration of the query/return. It is expected that access to the USDCDI data elements is accurate and complete, that the total number of requests increases over time, and the duration of the query/return does not increase over time.

Measure 2: Management of Multiple Applications. This measure will trend the number of population service applications that connect to the certified API technology over time, assess the total number of FHIR® Bulk Data Access requests made, and understand the duration of the query/return across applications. The associated certification criterion in the pediatric care setting is:

Certification Criteria	Requirement
§ 170.315(g)(10) Standardized API for patient and population services (population services only)	(i) Data response
	(ii) Supported search operations
	(iii) Application registration (EHR launch for FHIR® Bulk Data Access and Backend Services)

- **Justification:** The metric will be an indication of whether the group-export is working correctly across multiple applications registered to the certified API technology. This metric will provide proof that USCDI data is being accessed using the FHIR® Bulk Data Access standard required by § 170.315 (g)(10), provide insight into which set of USCDI parameters are accessed the most, and identify any issues related to accessing the USCDI data.
- **Test methodology:** Logs will be reviewed to determine trends on data types viewed within the Child Wellness Population App and identify reoccurring barriers to information (if any) by users. Additionally, log/use data will be used to trend the number of Bulk Data Access requests across multiple applications and examine query/return across applications.

- Expected outcome(s): Based on the log files, it is expected that the number of population service applications connected to certified API technology increase over time, that the total number of FHIR® Bulk Data Access requests made increases, and the duration of the query/return across applications is consistent.

REAL WORLD TESTING: SCENARIO 2 – MULTIPLE CRITERIA

Scenario 2 provides an example of a Real World Testing plan for several certification criteria: § 170.315(b)(1) Transitions of care; § 170.315(b)(9) Care plan; § 170.315(b)(10) Electronic Health Information (EHI) export; and § 170.315(e)(1) View, download, and transmit to 3rd party. To cover all the criteria, multiple use cases are required for this plan. Use Case 1 demonstrates the sharing of EHI for a single patient, while Use Case 2 demonstrates the sharing of EHI for a patient population.

Use Case 1 (Patient Services) Overview: A Certified Health IT developer has developed a case management system to ensure the timely availability of patient information within the cardiology care setting. This Certified Health IT Module is for use in situations where documentation needs to be coordinated between providers and patients both within and outside of a healthcare organization. The shared documentation includes transitions of care documents, healthcare plan documents, health information provided to the patient through a portal, and the export of patient healthcare records. The transitions of care documents are shared between organizations using Edge protocol technology (Direct, SMTP email) and with the patient through a portal with the ability to view, download, and transmit. Additionally, the patient health information can be shared with external organizations using an export function.

Use Case 2 (Population Services) Overview: In addition to the sharing of EHI on a patient level, the application also allows for the export of patient information on a population level. This function is not part of the standard workflow associated with the document sharing. However, to support the migration of the document system, or a research request, the Certified Health IT Module is capable of exporting the health information for the patient population.

Sample Real World Testing Plan Elements

The remaining sections of this document detail the overall approach a fictional Certified Health IT developer is taking for their Real World Testing. The information below includes Real World Testing elements as Certified Health IT developers should/could express them in their Real World Testing plans.

Justification for Real World Testing Approach

At this time, the Certified Health IT Module is sold to the cardiology specialty care setting. For this reason, the Real World Testing plan will apply to this specialty care setting. Since the case management system works on all types of documents, there are several certification criteria that can be tested simultaneously. All criteria involving the Consolidated Clinical Document Architecture (C-CDA) documents will be tested, including § 170.315(b)(1) Transitions of care, § 170.315(b)(9) Care plan, and § 170.315(e)(1) View, download, and transmit to 3rd party. Additionally, the case management system does support the export of EHI, so Real World Testing has been included for the criterion, § 170.315(b)(10) Electronic Health

Information export. Verification of the created patient record export does require interaction with a system external to the organization (and with a different vendor).

Standards Updates (SVAP and USCDI)

Standard (and version)	All standards versions are those specified in USCDI v1. The developer plans to use SVAP to update its (e)(1) module to support the new version of the Direct transport protocol (now known as Secure Health Transport) during the testing period.
Method used for standard update	SVAP
Date of ONC-ACB notification	April 2022
Date of customer notification (SVAP only)	April 2022
USCDI-updated criteria	The plan documents the support of all USCDI v1 data elements.

Care Setting(s)

Cardiology Specialty Care Setting: The case management system supports the deployment and tracking of documentation within and outside of the cardiology specialty setting.

Overall Expected Outcome(s)

- Real World Testing will demonstrate that the Health IT Module is conformant to the following certification criteria: § 170.315(b)(1) Transitions of care, § 170.315(b)(9) Care plan, § 170.315(b)(10) EHI export, and § 170.315(e)(1) View, download, and transmit to 3rd party.
- Real World Testing will demonstrate the ability of an external organization to use the EHI export as described in § 170.315(b)(10).
- Real World Testing will demonstrate that the Health IT Module supports SVAP for Direct.

Schedule of Key Milestones

Key Milestone	Date/Timeframe
Release of documentation for the Real-World Testing to be provided to authorized representatives and providers. This includes surveys, specific instructions on what to look for, how to record issues encountered, and Customer Agreements.	December 1, 2021
Collection of information as laid out by the plan for the period.	January 1, 2022
Planned System updates to allow for collection of data after a SVAP update.	March 1, 2022
Follow-up with providers and authorized representatives on a regular basis to understand any issues arising with the data collection.	Quarterly, 2022
End of Real-World Testing period/final collection of all data for analysis.	January 1, 2023
Analysis and report creation.	January 15, 2023

Key Milestone	Date/Timeframe
Submit Real World Testing report to ACB (per their instructions)	February 1, 2023

Measures Used

The following outlines the measures that have been identified to best demonstrate conformance to multiple certification criteria concerning the sharing of EHI (§ 170.315(b)(1), § 170.315(b)(9), § 170.315(e)(1), and § 170.315(b)(10)) across the two use cases demonstrated (single patient and population services).

Use Case 1 (Single Patient) Metrics: As part of the Real World Testing requirements for § 170.315(b)(1), § 170.315(b)(9), § 170.315(e)(1), and § 170.315(b)(10), the developer has developed the following metrics for their testing plan:

Measure 1: Sharing. This measure will catalogue the transport mechanisms used to share transitions of care documents and EHI, as well as track usage of the various transport mechanisms. Associated certification criteria for the case management system in a specialty care setting include:

Certification Criteria	Requirement
§ 170.315(b)(1) Transitions of care	(i)(A) Send transition of care/referral summaries
	(i)(B) Receive transition of care/referral summaries
§ 170.315(e)(1) View, download and transmit	(i)(B)(2) Download ambulatory summary or inpatient summary using CCD Template
	(i)(B)(3) (inpatient setting only) Download of transition of care/referral summaries
	(i)(C)(1) Transmit to third party
	(i)(C)(2) (inpatient setting only) Transmit transition of care/referral summaries

- **Justification:** The case management system includes two functionalities of interest: (A) Send transition of care/referral summaries and (B) Receive transition of care referral summaries, including (C) XDM processing. Transitions of care documents are shared using Edge protocols (e.g., SMTP, Direct) while other EHI may be shared through the patient portal using downloads and encrypted or unencrypted transmissions. This metric will provide information on the types of transmissions deployed (e.g., what types of Edge protocols, downloads and unencrypted vs. encrypted transmission) and the frequency of usages.

- Test methodology: Case management logs, system logs, and email logs will be reviewed to determine the frequency and the transport mechanism used by providers for sending/receiving transitions of care using Edge protocols and downloading or transmitting EHI by patients using the patient portal. Log files obtained during Real World Testing will be de-identified and used for analysis in several areas to validate the proper operation of the transport mechanisms and input for the calculation of the metric on the specific types of transport mechanisms used. This test methodology will primarily test the conformance of the implementation.
- Expected outcome(s): It is expected that providers and patients (or their authorized representatives) will be able to share EHI using the transmission mechanisms provided. Error rates will be tracked and trended over time.

Measure 2: Single Patient Export. This measure will assess functionality used to export EHI for a single patient. The associated certification criterion is:

Certification Criteria	Requirement
§ 170.315(b)(10) EHI export – Single patient EHI export	(i)(A) Create an export file
	(i)(B) Execute at any time
	(i)(C) Limit ability of users who can create export
	(i)(D) Electronic and computable format

- Justification: The export of EHI associated with a patient is another way to share information with an external organization. Export is typically used when there is a need for a full patient record. This metric will provide information on the type of data exported for a single patient and the frequency of usage.
- Test Methodology: Case management logs and system logs will be reviewed for each period to determine the frequency of use. Log files obtained during Real World Testing will be de-identified and used for analysis in several areas to validate the proper operation of the export. This test methodology will primarily test the conformance of the implementation.
- Expected outcome(s): It is expected that authorized users will be able to share EHI using the export function. Error rates will be tracked and trended over time.

Use Case 2 (Population Services): As part of the Real World Testing requirements for § 170.315(b)(10), the developer has developed the following metrics for their testing plan:

Measure 1: Patient Population Export. This measure will assess the functionality used to export EHI for a patient population. The associated certification criterion is:

Certification Criteria	Requirement
§ 170.315(b)(10) EHI export – Patient population EHI export	(ii)(A) Create an export file

- Justification: The export of the health information associated with a patient population is another way to share health information with an external organization. It is typically used for research or quality purposes to look for specific trends on patient population. Export of a patient population is an administrative function only available to credentialed users. It is assumed that this function will be run as a scheduled activity as it will have significant impact on the Health IT Module. This will provide a metric on the use of the export of EHI for a patient population associated with the Health IT Module.
- Test methodology: Case management logs and system logs will be reviewed to ensure the export function is operating properly and to determine the frequency of use. Log files obtained during Real World Testing will be de-identified and used for analysis in several areas to validate the proper operation of the export. This test methodology will primarily test the conformance of the implementation.
- Expected outcome(s): It is expected that authorized users will be able to share EHI for a patient population using the export function. Errors in transmission will be tracked and analyzed.