Real World Testing

Overview

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Please Note:

- The materials contained in this presentation are based on the provisions contained in 45 C.F.R. Parts 170 and 171. While every effort has been made to ensure the accuracy of this restatement of those provisions, this presentation is not a legal document. The official program requirements are contained in the relevant laws and regulations. Please note that other federal, state and local laws may also apply.

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What is Real World Testing?

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 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.

Successful Real World Testing means…

- Certified health IT continues to be compliant with the certification criteria, including the required technical standards and vocabulary code sets;

- Certified health IT is exchanging electronic health information (EHI) in the care and practice settings for which it is marketed for use; and

- Electronic health information (EHI) is received by and used in the certified health IT

(from 85 FR 25766)

Who is Required to Conduct Real World Testing?

CONDITION OF CERTIFICATION

A developer with Health IT Module(s) certified to one or more of the applicable certification criteria* **must** successfully test the real-world use of the technology for interoperability in the type of setting in which such technology is marketed.

*Any of the certification criteria outlined in § 170.405(a); summarized on next slide

MAINTENANCE OF CERTIFICATION

ONC- ACB - Authorized Certification Body
CHPL - Certified Health IT Product List

A Certified Health IT Developer **must**:

(1) Submit its Real World Testing plan to its ONC-ACB by a date that enables the ONC-ACB to publish the plan on the CHPL no later than December 15 of each calendar year.

(2) Submit its Real World Testing results to its ONC-ACB by a date that enables the ONC-ACB to publish the results on the CHPL no later than March 15 of each calendar year.

(3) Notify the responsible ONC-ACB of any non-conformity with Certification Program requirements.

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

Patient Engagement

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

Clinical Quality Measures

- ✓ § 170.315(c)(1)—record and export
- ✓ § 170.315(c)(2)—import and calculate
- ✓ § 170.315(c)(3)—report

Electronic Exchange

- ✓ § 170.315(h)(1) Direct Project
- ✓ § 170.315(h)(2) Direct Project, Edge Protocol, and XDR/XDM

Application Programming Interfaces (APIs)

- ✓ § 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

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

Real World Testing Plan – Included Health IT Modules

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.

This process is required on an ongoing, yearly basis for all Health IT Modules certified to applicable certification criteria. See below for a review of the cycle from plan to results report.

Plan — Design and submit a Real World Test plan

Conduct Testing — Gather data proposed in submitted test plan

Report — Submit test plan results

2021

★ Plan Available

2022

⬡ Results Available

2023

08/31/2021
Certification Deadline for 2022 Real World Testing

12/15/2021
Deadline for 2022 Real World Testing Plan to be made publicly available on CHPL

08/31/2022
Certification Deadline for **2023 Real World Testing**

12/15/2022
Deadline for **2023 Real World Testing Plan** to be made publicly available on CHPL

Real World Testing Lifecycle

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.

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 they do so after the August 31st deadline and certify a newer version of a Real World Testing-eligible product, that newer version inherits the Real World Testing requirement along with its certification.

Developers that choose to update via ICS should include that newer product in the Real World Testing cycle for which the older product was eligible.

Inherited Certified Status

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

October 2021

Module X is certified.

December 15, 2022

Developer submits Real World Testing plan for Module X.

March 15, 2024

Developer includes Module Y in Real World Testing results report as a modification from the original plan.

2023 Real World Testing

Module X meets eligibility requirements to be included in 2023 Real World Testing.

Developer certifies Module Y, a newer version of Module X, under ICS.

Developer withdraws Module X.

August 31, 2022

April 2023

Real World Testing Plan – Included Health IT Modules

FAQ: Can I submit a testing plan for the following calendar year for a Health IT Module and/or certification criteria certified after August 31?

- At a minimum, developers must include in their Real World Testing plan for the following calendar year all health IT certified as of August 31.

- Developers may include in their Real World Testing plan for the following calendar year any Health IT Modules and/or certification criteria certified after August 31, but this is not required.

- Developers that choose to include updates made after the August 31 deadline in their testing plan for the following calendar year, must also include those Modules and/or certification criteria as part of requirements in their next cycle of Real World Testing.

- Real World Testing is required for all health IT Modules certified as of August 31 of each year regardless of whether they were included in previous years' Real World Testing Plans.

- Updates made after the August 31st deadline using the Inherited Certified Status flexibility will still be subject to Real World Testing the following year.

Designing and Submitting a Real World Testing Plan

Real World Testing Resources – Plan Template

This **optional** template is available to assist developers with the creation of their Real World Testing plan by outlining all necessary elements required for submission.

Each section provides a field for submitting responses and/or explanations for how the Health IT Developer will address each required element in their Real World Testing approach.

Note: ONC-ACBs may have additional requirements for submission. Confirm all requirements with your respective ONC-ACB before submission.

https://www.healthit.gov/sites/default/files/page/2021-07/Real-World-Testing-Plan-Template.pdf

Health IT Certification Program
The Office of the National Coordinator for Health Information Technology

required for developing a Real World Testing plan and can be expanded with additional rows or columns to address the specific needs of the Real World Testing plan being submitted.

GENERAL INFORMATION

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

Developer Name:

Product Name(s):

Version Number(s):

Certified Health IT:

Product List (CHPL) ID(s):

Developer Real World Testing Page URL:

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

Provide an explanation for the overall approach to Real World Testing, including an outline of the approach and how data will be used to demonstrate successful Real World Testing[i].

All measures should reasonably align with the elements within a Real World Testing plan, the scope of the certification, the types of settings in which the certified health IT is marketed, and other factors relevant to the implementation of the certified Health IT Module(s). The justification should reflect how each element within the plan is relevant to the developer's overall strategy for meeting the Real World Testing Condition and Maintenance of Certification requirements.

Note: A single Real World Testing plan may address multiple products and certification criteria for multiple care settings.

Real World Testing Resources – Results Report Template

This **optional** template is available to assist developers with the creation of their Real World Testing results report by outlining all necessary elements required for the submission of a complete results report.

Note: ONC-ACBs may have additional requirements for submission. Confirm all requirements with your respective ONC-ACB before submission.

https://www.healthit.gov/sites/default/files/page/2021-08/Real-World-Testing-Results%20Report-Template_2022.pdf

Real World Testing Plan and Results Deadlines

Real World Testing plans must be publicly available on the CHPL **by December 15th of each year.** Developers have one year to complete their testing of their submitted plan(s).

Real World Testing results must then be publicly available on the CHPL **by March 15th of each year** following their year of testing.

NOTE: For both testing plans and results ONC-ACBs will determine a date by which the plans and results report must be submitted in order to allow time to review for completeness before making publicly available.

2021   Plan Available   **2022**   Results Available   2023

8/31/2021
Certification Deadline for 2022 Real World Testing

12/15/2021
Deadline for 2022 Real World Testing Plans to be made publicly available on CHPL

3/15/2023
Deadline for 2022 Real World Testing Results to be made publicly available on CHPL

ONC-ACB specific deadline to submit
2022 Real World Testing Plans
(varies by ONC-ACB)

ONC-ACB specific deadline to submit 2022 Real World Testing Results
(varies by ONC-ACB)

Landing Page for Real World Testing Plans

- Developers must make past and current plans and results reports available via a URL hosted on the CHPL.

- The CHPL allows for publication of one link for plans and one link for results report.

- **To ensure continued access to current and previous years' plans and results reports, developers should provide a single link on the CHPL that directs to a landing page with access to all documents.**

- Developers have the option to include plans and results reports at the same link or may create two separate links if appropriate. Links can also host plans/results reports for all products that are eligible for Real World Testing.

Real World Testing – Plan Elements

Health IT Developers must address the following elements for each certification criterion applicable to the Health IT Module's scope of certification in their Real World Testing plan.

Standards Updates

Testing Methodology(ies)

Associated Certification Criteria

Description of Measurement/Metric(s) Used

Care Setting(s)

Justification for Approach

Expected Outcomes

Key Real World Testing Milestones

FR §170.405(b)(1)(iii)

Designing a Real World Testing Plan – 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.

Factors to Determine 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
- Certification criteria measured (individually or concurrently)
- Health IT Modules addressed (individually or concurrently)

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. Thus, real patient data and real production environments should be first considered when developing Real World Testing plans.*

Developers are discouraged from using test tools and platforms as part of the Real World Testing process. These 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.

Use of real patient data does not require use of identifiable data. Identifiable patient data should not be included in plans or results reports. This guidance suggests that the measure of real-world use should be based off production data instead of synthetic data.

Designing a Real World Testing Plan – Standards Updates

The ONC Cures Act Final Rule requires developers to update their Certified Health IT Modules to new standards for specific certification criteria.

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.

How to ensure certified health IT is updated:

✓ Review the 2015 Edition Cures Update for relevant criteria updates and associated timelines for your Health IT Modules.

✓ Work with your ONC-ACB to ensure all updates to selected criteria cover the scope of certification.

✓ Notify customers of updates to respective products.

✓ Once updates are complete, ONC-ACB will update product status on the CHPL.

✓ Developers should account for updates in their Real World Testing Plan. Updated criteria should be integrated into measures.

Designing a Real World Testing Plan – Standards Updates: December Deadline

Required updates exist for the following sections related to the 2015 Edition Certification Criteria. These must be updated and made available to your customers by <u>December 31, 2022,</u> to remain in compliance.

USCDI Updates

Updated Criteria: Updates required to support USCDI v1 for Health IT Modules certified to § 170.315(b)(1), (b)(2), (e)(1), (f)(5), (g)(6) and/or (g)(9).

C-CDA Companion Guide Updates

Updated Criteria: Updates required to support Consolidated Clinical Document Architecture (C–CDA) Companion Guide for Health IT Modules certified to § 170.315(b)(1), (b)(2), (b)(9), (e)(1), (g)(6), and/or (g)(9).

Electronic prescribing

Updated Criterion: Updates required to support the National Council for Prescription Drug Programs (NCPDP) SCRIPT Version 2017071 for Health IT Modules certified to the § 170.315(b)(3).

Security tags

Updated Criteria: Updated to revised versions are required for Health IT Modules certified to § 170.315(b)(7) and/or (b)(8)

ASTM updates

Updated Criteria: Updates required to support ASTM E2147—18 for Health IT Modules certified to § 170.315(d)(2), (d)(3), and/or (d)(10).

Clinical Quality Measures – Report

Updated Criterion: Updates required to support CMS QRDA Implementation Guide for Health IT Modules certified to § 170.315(c)(3).

Real World Testing – Standards Updates: SVAP

Standards Version Advancement Process (SVAP)

This **voluntary process** 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. SVAP is only available for ONC-approved newer versions of adopted standards.

Details about the SVAP and Approved 2020 SVAP Versions for Health IT Certification can be found under the **Certification Criteria section of the ONC website:** https://www.healthit.gov/topic/standards-version-advancement-process-svap

SVAP Updates and Real World Testing

FAQ: If I want to update to a newer approved standard via SVAP, is that accomplished through the Real World Testing activities? Are there any other steps I should consider?

Real World Testing does not serve as the update method for SVAP; it is an activity to demonstrate conformance once the updates made via SVAP. To take advantage of the flexibility to update to newer approved versions, a developer must:

- Provide advance notice to all affected customers and its ONC-Authorized Certification Body (ONC-ACB)
  - ✓ expressing intent to update to the more advanced version of the standard;
  - ✓ expectations for how the update will affect interoperability of each affected Health IT Module;
  - ✓ whether 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.
- Work with its ONC-ACB to update information included in its CHPL listing
- Maintain the updated certified Health IT Module(s) in full conformance with all applicable Certification Program requirements.

Once these steps have been taken, the SVAP updates should be reflected in your Real World Testing plan.

Designing a Real World Testing Plan – Standards Updates

The following should be submitted for each standard included in a developer's Real World Testing plan:

- ✓ Standard and version

- ✓ Certification criteria in which product(s) has been updated

- ✓ If reporting for multiple products, identify the certification criteria that were affected by the update for each of the associated products

- ✓ CHPL Product Number for each Health IT Module

- ✓ Method used for standard update (e.g., SVAP)

- ✓ Date notification sent to ONC-ACB

- ✓ Date notification sent to customers (SVAP only)

- ✓ Measure used to demonstrate conformance with updated standard(s)

- ✓ Which certification criteria were updated to USCDI and/or to which version of USCDI was the certification criteria updated

Designing a Real World Testing Plan – Identifying Measures

Developers have flexibility in selecting measures but should keep in mind the following:

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

➢ **Each applicable certification criterion must be addressed** in a measurement or metric. 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.

➢ **Each type of care setting in which their certified health IT is marketed must be addressed**, but each setting does not necessarily have to be measured or represented in every measure or metric that is part of the plan.

➢ Measurements/metrics can be **combined in many ways to yield results**. One measure could potentially address multiple criteria and care settings.

➢ Measures/metrics should **demonstrate ongoing interoperability and functionality** relative to the certification criteria.

➢ Where possible, measures should include a **defined denominator to serve as a baseline for understanding the context in which the testing occurred**.

Designing a Real World Testing Plan – Identifying Measures

	Favorable Factors	Unfavorable Factors
Type of Data	✓ Real patient data ✓ Rate of success/failure ✓ Number of errors compared to successes over time	x Yes/no x Pass/fail x Use of test tool as proxy measure
Collection Method	✓ Data derived from networks that developers participate in ✓ Data derived from use of test tools	x Surveillance results indicating conformity/non-conformity x Single instance of demonstrating interoperability or data exchange

Designing a Real World Testing Plan – Identifying Measures | Special Scenarios

Certain scenarios specific to your Health IT Module may inform what measures you select to include in your Real World Testing plan.

Resellers of Certified Products

Relied Upon or Third Party Software

Cloud-based Products

Products with Non-deployed Capabilities or Low Adoption of Capabilities

Designing a Real World Testing Plan – Identifying Measures | Special Scenarios

Certain scenarios specific to your Health IT Module may inform what measures you select to include in your Real World Testing plan.

**Relied Upon or
Third Party Software**

Any relied upon software used to demonstrate conformity with certification **must be included and addressed as part of Real World Testing** in order to verify the full scope of a Module's applicable certification criteria and functions.

This should be identified along with the associated certification criteria for any metric(s) defined in a developer's Real World Testing plan.

Designing a Real World Testing Plan – Identifying Measures | Special Scenarios

Certain scenarios specific to your Health IT Module may inform what measures you select to include in your Real World Testing plan.

Cloud-based Products

Cloud-based products that offer the same deployed capability across multiple types of care settings will be **required to test the same capability for those different types of settings.**

Designing a Real World Testing Plan – Identifying Measures | Special Scenarios

Certain scenarios specific to your Health IT Module may inform what measures you select to include in your

Real World Testing plan.

**Resellers of
Certified Products**

- Developers are responsible for communicating any Real World Testing requirements for their re-marketed product(s) to their partners/distributors.
- ONC does not specify whether a reseller or the original developer is required to fulfill Real World Testing.
- ONC permits the inheritance of plans and results by developer's authorized resellers.
- If the reseller markets in different setting than the original developer, it is the reseller's responsibility to ensure those settings are addressed in Real World Testing (either conducting such Testing or providing evidence that the original developer has conducted this Testing)
- Check with your ONC-ACB for any additional requirements around reseller reporting.

Designing a Real World Testing Plan – Identifying Measures | Special Scenarios

Certain scenarios specific to your Health IT Module may inform what measures you select to include in your Real World Testing plan.

**Products with
Non-deployed Capabilities or
Low Adoption of Capabilities**

- There may be instances where a developer may market capabilities that are required for certification but have not yet been deployed or are not used by their customers. These **capabilities should still be addressed in a developer's Real World Testing plan**.
- Developers have **flexibility in determining how to meet these Real World Testing requirements** in a way that minimizes burden on users while optimizing value of the testing activities.
- This flexibility includes, though is not limited to, the use of 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.

Use of real patient data does not require use of identifiable data. Identifiable patient data should not be included in plans or results reports. This guidance suggests that the measure of real-world use should be based off production data instead of synthetic data.

Designing a Real World Testing Plan

Measure Description

✓ Describe the measure, the metric or data collected, time period of measurement, associated certification criteria, any relied upon software for the criteria, justification and expected outcomes.

✓ Consider how the data, metrics and measurements will work together to produce the evidence needed to demonstrate successful interoperability and functionality.

Justification for Measure and Approach

✓ Provide 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).

✓ Demonstrate how the measure is relevant to the overall strategy for meeting the Real World Testing Condition and Maintenance of Certification requirements.

Associated Certification Criteria

✓ Articulate the certification criteria addressed in each measure and whether any relied upon software is used to meet that criterion's requirements.

✓ If a single measure is used for multiple Health IT Modules, clearly identify which Modules are also associated with the measure.

✓ ONC recommends an inventory of measures, criteria and associated Modules be included in plans and results reports for easier ONC-ACB completeness review.

Designing a Real World Testing Plan – Care Settings

Health IT Developers must consider all setting types in which their product is marketed when determining their testing approach.

Not each setting marketed must be included in Real World Testing, but plans should **address each type of clinical setting in which the certified health IT is marketed**.

Developers must provide justification for their choice of care and/or practice settings and chosen approach for each measure.

When considering care settings for testing:

- Settings or healthcare provider types are not excluded from Real World Testing requirements based on (in)eligibility for any specific federal healthcare program or initiative.

- 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.

Designing a Real World Testing Plan – Care Settings

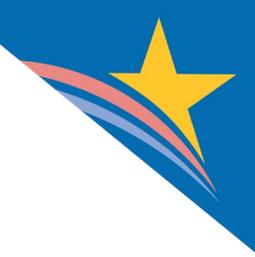**FAQ:** What care settings should be included in my Real World Testing plan?

- ONC does not specifically define or limit the care settings and leaves it to the health IT developer to determine.

- As an example, Health IT Developers can consider categories, including but not limited to:
  - those used in the Promoting Interoperability Programs;
  - long-term and post-acute care;
  - pediatrics;
  - behavioral health; and/or
  - small, rural, and underserved settings

85 FR 25769

Designing a Real World Testing Plan – 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;

- Also reflect what should not be a result of a given action;

- Be 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.

Designing a Real World Testing Plan – Schedule and 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.

Key milestones should be relevant and directly related to expected outcomes.

Sample Milestones may include:

- 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 dates,
- Completion of testing phases;
- End of Real World Testing period/final collection of all data for analysis; and
- Analysis and report creation.

Post-Plan Submission: Considerations during Testing and Creation of Results Report

Real World Testing Non-conformities

Non-conformities may be discovered during Real World Testing.

If this occurs, ONC-ACBs have processes in place to help developers self-report non-conformities in a timely manner and work with the developers to have them corrected.

How it works:

- Familiarize yourself with your ONC-ACB's process for self-reported non-conformities.
- Communicate non-conformity findings to ONC-ACB within 30 days of discovery.
- Work with ONC-ACB to develop a plan to correct.

Health IT developers must report any non-conformity(ies) found during Real World Testing to the ONC-ACB within 30 days (§ 170.405(b)(2)(i))

Real World Testing Results Reports – Key Elements

There are specific elements that developers must include in their Real World Testing results report for it to be considered complete.

- 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)

- 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

More information about results reporting to come later this fall!

Real World Testing Results Report –
Reporting Changes to Testing Plan

FAQ: I submitted my plan but now that testing has begun, our approach doesn't fit the needs to successfully test the real-world setting. Am I allowed to stray from the submitted plan? Do I need to submit a modified plan?

- Throughout Real World Testing activities, there will be instances where developers may find a need to modify their testing methodologies or approaches that were originally laid out in their plans to address unexpected changes during their testing period.

- The developer is not prohibited from adjusting their approaches following submission, **however** ONC will not post updated plans on CHPL outside of the submission deadline.

- **Any adjustments to the approach should be included in the results report**, explaining:

    - The type of changes made;

    - The reasons for these changes; and

    - How the intended outcomes were more efficiently met as a result of these changes

- Check with your ONC-ACB for any additional considerations when handling these adjustments.

Real World Testing Results Reports – Inclusion of Withdrawn Products

In some cases, a developer may withdraw a Real World Testing-eligible product 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 Product Number(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 can 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.

Further Review:
Real World Testing Resources

Real World Testing Resources – Resource Guide

This Resource Guide aims to assist developers in organizing the required elements related to the submission of a Real World Testing plan to support the Conditions and Maintenance of Certification for their applicable Health IT Modules.

Items outlined in the guide include:

- Timeline requirements
- Details on the plan elements needed to meet requirements
- Guidance on special considerations for unique product(s), customer(s) and/or setting(s)
- Sample scenarios to illustrate the creation of a Real World Testing plan to support testing for:
  - Health IT Modules that must complete Real World Testing for a single certification criterion
  - Health IT Modules that must complete Real World Testing for multiple certification criteria

2022 Resource Guide Updates include:

NEW IN 2022!

- Greater clarity on inclusion of ICS products in Real World Testing
- Importance of creating a landing page for plans/results reports
- More examples on what to include in metrics
- Initial guidance on considerations for the creation of results reports, including:
  - How to document changes to your plan
  - How to address products that had been withdrawn since the initial plan submission

Real World Testing Resources

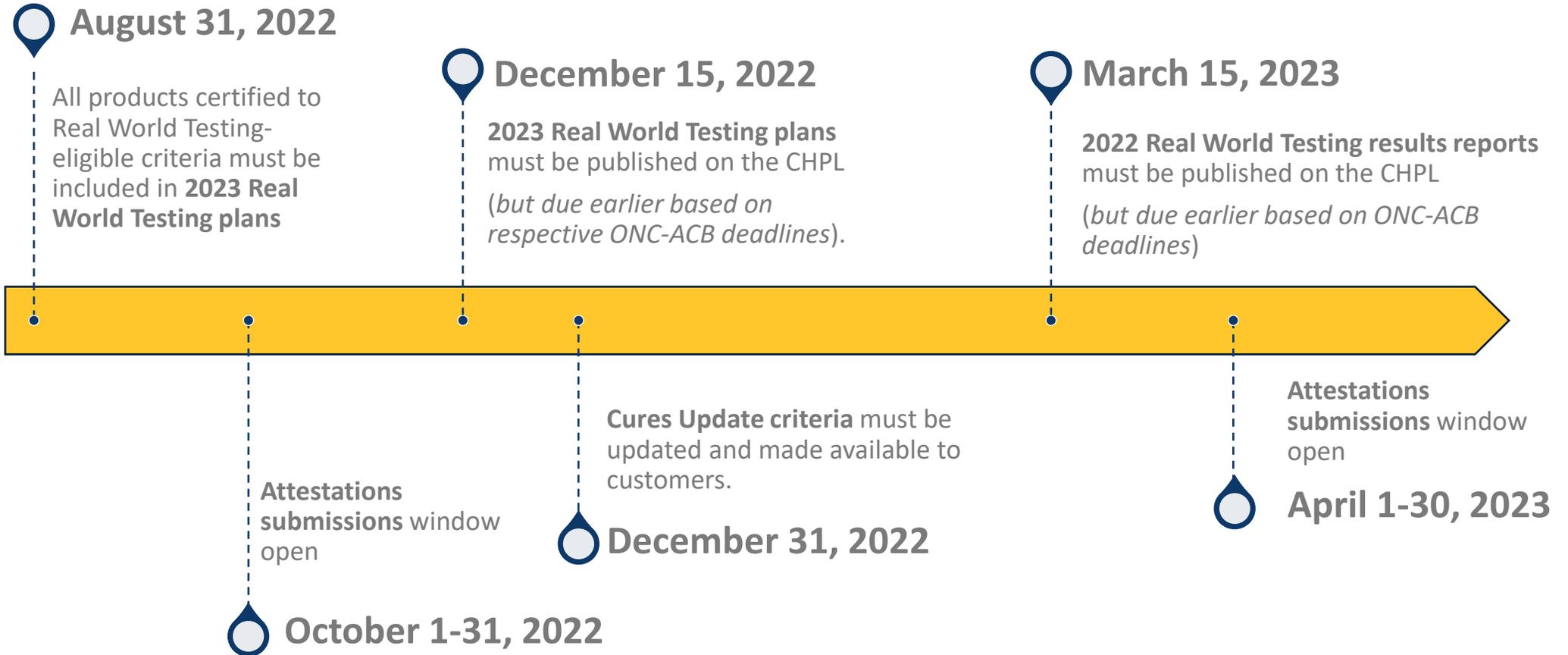Visit https://www.healthit.gov/topic/certification-ehrs/real-world-testing for access all the materials discussed and more.

- **Fact Sheet – What it Means for Health IT Developers**

- **Plan Template –** *Updated!*

- **Results Report Template –** *New!*

- **Resource Guide –** *Updated!*

- **Real World Testing Certification Companion Guide**

- **Previous Webinar Recording and Slides**

Key Certification Program Compliance Dates 2022 and Beyond

August 31, 2022

All products certified to Real World Testing-eligible criteria must be included in **2023 Real World Testing plans**

December 15, 2022

2023 Real World Testing plans must be published on the CHPL

(*but due earlier based on respective ONC-ACB deadlines*).

March 15, 2023

2022 Real World Testing results reports must be published on the CHPL

(*but due earlier based on ONC-ACB deadlines*)

Attestations submissions window open

October 1-31, 2022

Cures Update criteria must be updated and made available to customers.

December 31, 2022

Attestations submissions window open

April 1-30, 2023

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