Real World Testing

Results Reporting

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Please Note:

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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

A developer with Health IT Module(s) certified to one or more of these certification criteria by August 31 **must** include those criteria in their Real World Testing plans for the upcoming year.

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

Public Health

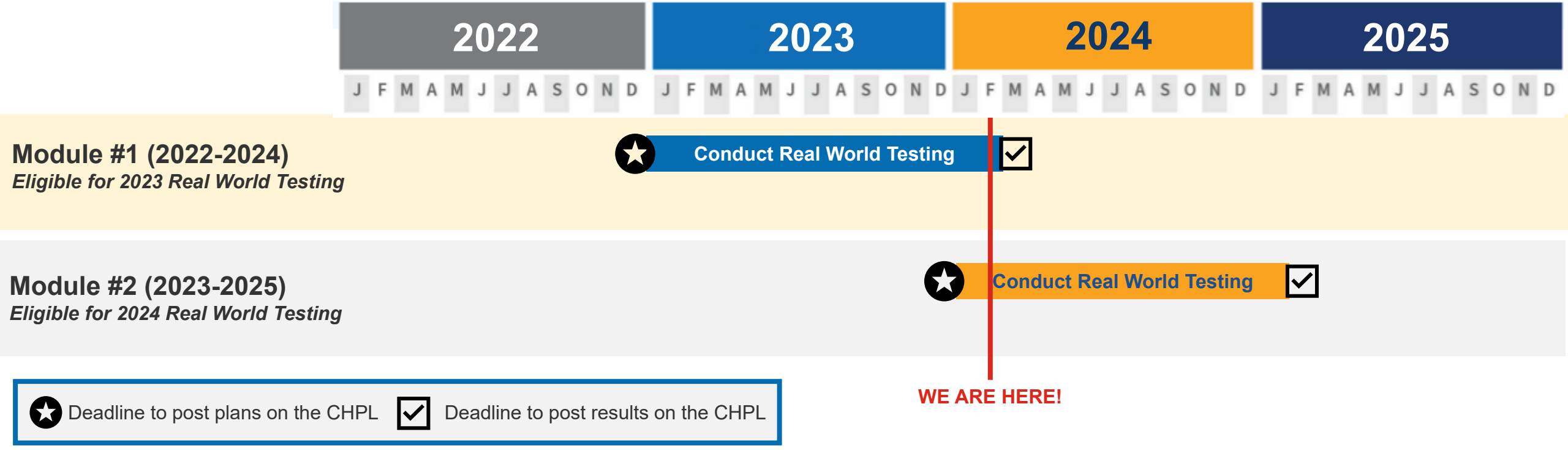
- ✓ § 170.315(f)(1) Transmission to immunization registries
- ✓ § 170.315(f)(2) Transmission to public health agencies – syndromic surveillance
- ✓ § 170.315(f)(3) Transmission to public health agencies – reportable laboratory tests and value/results
- ✓ § 170.315(f)(4) Transmission to cancer registries
- ✓ § 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 Lifecycle

The Real World Testing process occurs on an ongoing, yearly basis for all Health IT Modules certified to applicable certification criteria. The results submitted should be based on and directly related to the Real World Testing plan submitted for the immediately preceding calendar year.

Real World Testing plans must be publicly available on the CHPL **by December 15th of each year.** Developers have one year to complete the testing process submitted in their plan(s). **Real World Testing results** must 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 to allow time to review for completeness before making publicly available.



Inherited Certified Status (ICS)

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 must include that newer product in the Real World Testing cycle for which the older product was eligible.

Inherited Certified Status (ICS)

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 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:

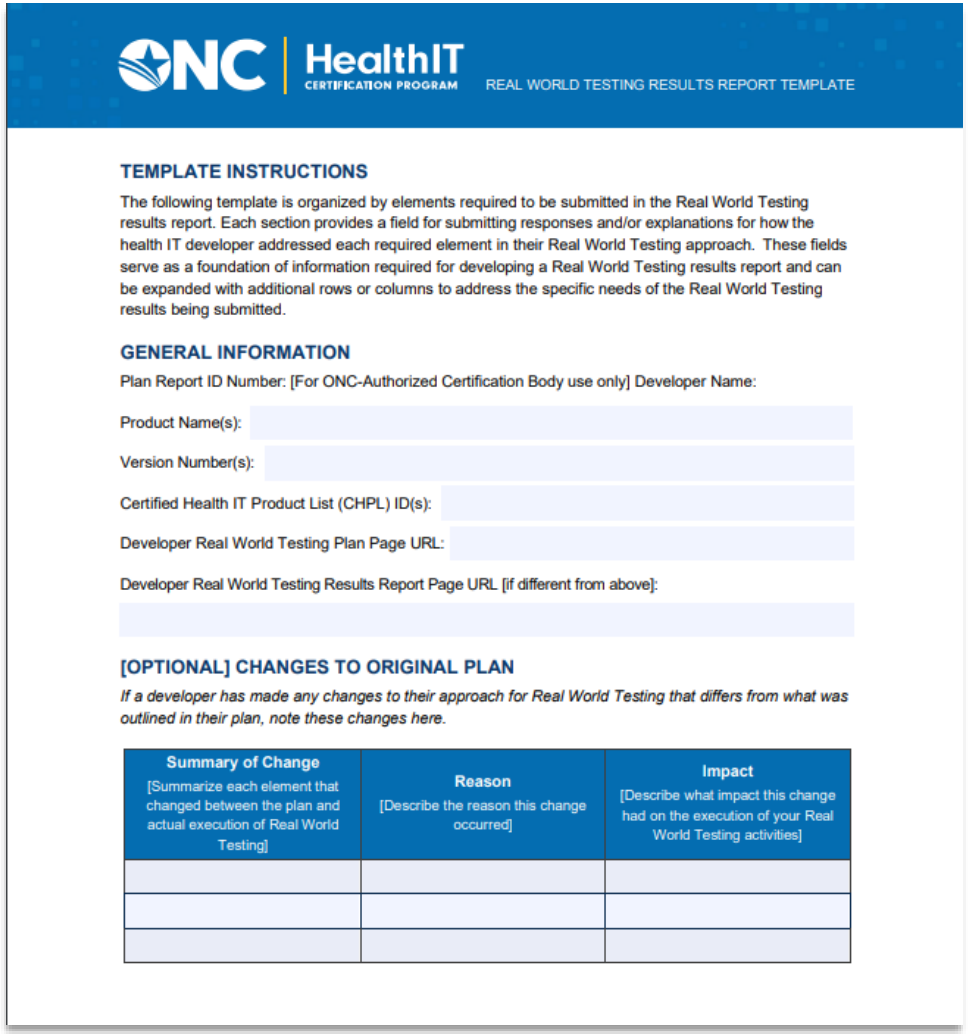
- Familiarize yourself with your ONC-ACB's process for self-reported non-conformities.
- Communicate non-conformity findings to ONC-ACB within 30 days of discovery.
- Work with ONC-ACB to develop a plan to correct.

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 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.



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REAL WORLD TESTING RESULTS REPORT TEMPLATE

TEMPLATE INSTRUCTIONS

The following template is organized by elements required to be submitted in the Real World Testing results report. Each section provides a field for submitting responses and/or explanations for how the health IT developer addressed each required element in their Real World Testing approach. These fields serve as a foundation of information required for developing a Real World Testing results report and can be expanded with additional rows or columns to address the specific needs of the Real World Testing results 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 Plan Page URL:

Developer Real World Testing Results Report Page URL [if different from above]:

[OPTIONAL] CHANGES TO ORIGINAL PLAN

If a developer has made any changes to their approach for Real World Testing that differs from what was outlined in their plan, note these changes here.

Summary of Change [Summarize each element that changed between the plan and actual execution of Real World Testing]	Reason [Describe the reason this change occurred]	Impact [Describe what impact this change had on the execution of your Real World Testing activities]

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

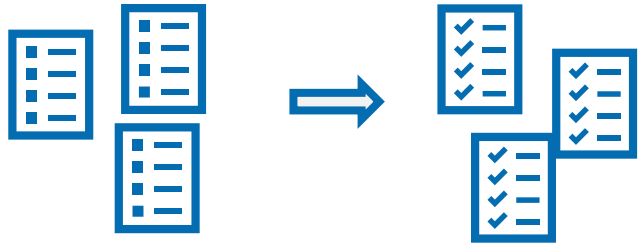
Designing a Real World Testing Results Report – One or Many?

Developers have flexibility to structure their Real World Testing plans in whatever way they think will best convey information. Some developers covered all products/versions/criteria in one Real World Testing plan, while others created multiple plans to represent their certified products.

Whatever approach a developer took in their plan design, ONC recommends they also follow that approach in their results report to allow for readers to easily connect between the two documents.

One Plan = One Results Report

Multiple Plans = Multiple Results Report



Regardless of the number of plans and results reports created, 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.

Designing a Real World Testing Results Report – Key Elements

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

Changes to Original Plan

Care Setting(s)

Key Real World Testing Milestones

Outcomes

Testing Methodology(ies)

Standards Updates

Measurement/Metric(s)

Designing a 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.

Designing a Real World Testing Results Report – 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 data exchange.

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.

Designing a Real World Testing Results Report – Standards Updates via SVAP

A Developer is permitted to update its Health IT Module(s) to newer versions of adopted standards if such standards have been approved by the National Coordinator via the Standards Version Advancement Process (SVAP). Developers that take advantage of SVAP must consider the following in their Results Reports.

For Results Reports, developers must:

- ✓ Indicate whether they made any voluntary updates to the standards for their certified products.
- ✓ Provide the following information if they did update standards:
  - ✓ Standard and version
  - ✓ Updated criteria and associate product
  - ✓ CHPL Product Number
  - ✓ How they measured conformance

Details about the SVAP and Approved 2023 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

Designing a Real World Testing Results Report – Care Settings

Real World Testing should have been conducted within each type of setting in which their product is marketed.

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

FAQ: What care settings should be included in my Real World Testing results report?

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 Results Report

Measurement/Metric

- ✓ Describe the measure, the metric or data collected, time period of measurement. Include the denominator for measurement to understand the context of results.
- ✓ Consider how the data, metrics and measurements will work together to produce the evidence needed to demonstrate successful interoperability and functionality.
- ✓ 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 for easier ONC-ACB completeness review.

Associated Certification Criteria

- ✓ Articulate the certification criteria addressed in each measure.

Relied Upon Software

- ✓ Articulate whether any relied upon software is used to meet that criterion's requirements.

Outcomes

- ✓ Demonstrate that the certified health IT is conformant with the certification criteria, including required standards and code sets.
- ✓ Demonstrate the certified products are exchanging electronic health information (EHI) in the settings for which it is marketed.
- ✓ Demonstrate EHI is received and used in the certified health IT.
- ✓ Detail any outcomes that did not result from their measurement approach if that better describes efforts.

Challenges Encountered

- ✓ Describe any challenges that may have arisen during Real World Testing that altered metrics collected and/or expected outcomes for the testing.

Designing a Real World Testing Results Report – Measures Used

As a reminder, measures should have been leveraged in testing that help demonstrate the real world use of certified health IT products.

	Favorable Factors	Unfavorable Factors
Type of Data	✓ Real patient data* ✓ Rate of success/failure ✓ Number of errors compared to successes over time ✓ Context for data provided	x Yes/no x Pass/fail x Use of test tool as proxy measure x No context for data provided
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

**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 Results Report – Outcomes

Health IT Developers detailed in their plans how the approaches chosen would produce outcomes that reflect successful Real World Testing.

In Results Reports, 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;
- 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.

Results Reports | Gold Standard Examples

170.315(b)(3) Electronic Prescribing

Product	[redacted]
Date Range of Metrics:	November 1, 2022 - December 31, 2022
Clients Sampled:	1,374
Adoption Rate:	75% of [redacted] clients are licensed for e-Prescribing
Method:	Summative Testing from [redacted] Transaction Logs & Message Dashboard

Testing Justification and Expected Outcome:
This criterion requires the ability of a certified Health IT module to perform prescription-related electronic transactions (eRx) using required standards. However, it is not possible to demonstrate the correct standards were used because it is not feasible to obtain copies of eRx documents from "outside" companies or pharmacies who have no incentive to participate. Therefore, we intend to demonstrate the required certified capabilities are effective by demonstrating how often eRx transactions are performed by examining reports from our eRx partner. This will demonstrate that not only are the eRx transactions sent fr the certified Health IT module, but that the transactions are successfully received by the eRx clearinghouse. Our expectation is there will be high utilization by providers with a hig success rate.

Testing Summary:

- A query on historical audit logs for a 2 month was performed for the 170.315(b)(3) criterion. The resulting totals show that this module was active throughout the perio and therefore demonstrates a compliant result.
- The [redacted] dashboard indicated a success rate of 99.8% for new prescriptions created, further demonstrating a compliant solution.

Success rate included in summary to support data.

Outlines data collection period clearly. Included number sampled and how many of their clients use this capability.
Remind reader of test methods..

Justification reiterated from plan to remind of limitations and expected outcomes.

Measure	Metric Value
Number of prescriptions created (NewRx)	5,284,763
Number of prescriptions changed (RxChangeResponse)	35,579
Number of prescriptions canceled (CancelRx)	515,734
Number of prescriptions renewed (RxRenewalResponse)	1,104,883

Provide numerical context for the criteria tested.

Results Reports | Needs Improvement

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

- *Measurement:* % of single/multiple patient data request
- *Outcome:* 100% successful

No explanation on how success is measured.
No definition of what the % refers to.
No denominator for sample. No numbers whatsoever regarding this criteria.

Users are able to record and export and import all of the data that would be necessary to calculate each CQM

During our testing, we did not discover any errors or criteria non-conformities. Our results reveal our EHR Module functionality is working as expected.

Practices Queried: 10

Practices Reporting Results/Utilizing Certification Functionality: 5

Average Result: 12.5

Median Result: 7.5

Unclear what the results are demonstrating. No explanation included in the report to explain these values under “Average Result” and “Median Result”

Generate a Clinical Quality Measure (CQM) Report	170.315 (c)(1): Clinical Quality Measures - Record and Export 170.315 (c)(3): Clinical Quality Measures – Report	The CQM report generated successfully without any errors. There were no complaints from the testing participants regarding the CQM measures. The data points associated with this measure provided evidence of ongoing Maintenance of Certification for Clinical Quality Measures: Report and Clinical Quality Measures: record and export.

No context around how many reports created, how many participants were included.
Reference to data points that demonstrate compliance but do not provide those data points.

Designing a Real World Testing Results Report – Key Milestones

Health IT Developers included 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.

Results Reports Key Milestones should include a list of key milestones that were met during the Real World Testing process.

Include details on how and when the developer implemented the measures and collected data.

Real World Testing Results Report – Special Scenarios

Certain scenarios specific to your Health IT Module may have informed what measures you selected to include in your Real World Testing plan and should be consider in the reporting of your results.

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 results report as they were in their plans**.
- 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.*

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
- Examples on metrics to consider
- Guidance on special considerations for unique product(s), customer(s) and/or setting(s)
- Details on the results report elements needed to meet requirements and how to:
  - Document changes from original plan
  - Address products that have been withdrawn since initial plan submission
- Guidance on inclusion of ICS products in Real World Testing
- 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

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**
- **Results Report Template**
- **Resource Guide**
- **Real World Testing Certification Companion Guide**
- **Previous Webinar Recording and Slides**

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