# *REAL WORLD TESTING RESULTS REPORT* TEMPLATE

#### **BACKGROUND & INSTRUCTIONS**

C HealthIT CERTIFICATION PROGRAM

Under the ONC Health IT Certification Program (Certification Program), health IT developers are required to conduct Real World Testing of their certified health IT (45 CFR 170.405). The Office of the National Coordinator for Health Information Technology (ONC) issues Real World Testing resources to clarify health IT developers' responsibilities for conducting Real World Testing, to identify topics and specific elements of Real World Testing that ONC considers a priority, and to assist health IT developers in developing their Real World Testing plans and results reports.

<u>A Real World Testing plan template</u> was created to assist health IT developers in organizing the required information that must be submitted for each element in their Real World Testing plan. To accompany the plan template, ONC has also provided this results report template.

While the use of this template is voluntary, health IT developers may find it useful in preparing their Real World Testing results report(s). Health IT developers must submit one year of results to address the Real World Testing of eligible products as outlined in their previous year's Real World Testing plan(s). If adjustments to approaches are made throughout Real World Testing, the health IT developer should reflect these adjustments in their Real World Testing results report. ONC expects that the results report will include a list of these changes, the reasons for them, and how intended outcomes were more efficiently met as a result.

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

- Real World Testing–What It Means for Health IT Developers Fact Sheet
- Real World Testing Resource Guide
- Real World Testing Certification Companion Guide

Health IT developers should also review the following regulatory materials, which establish the core requirements and responsibilities for Real World Testing under the Certification Program.

 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program final rule, <u>85 FR 25642</u> (May 1, 2020) (**ONC Cures Act Final Rule**) o <u>Section VII.B.5</u> — "*Real World Testing*"

#### **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): Perform+

Version Number(s): 23.3

Certified Health IT Product List (CHPL) Product Number(s): 15.04.04.2694.BICL.23.09.0.231107

Developer Real World Testing Plan Page URL: <u>https://f.hubspotusercontent30.net/hubfs/8759937/assets/pdfs/Real-World-Testing-Plan-</u> <u>Revised%20Signed.pdf</u>

Developer Real World Testing Results Report Page URL [if different from above]: <a href="https://8759937.fs1.hubspotusercontent-na1.net/hubfs/8759937/Perform%2B\_Regulatory\_Certificate/Real-World-Testing-Results">https://8759937.fs1.hubspotusercontent-na1.net/hubfs/8759937/Perform%2B\_Regulatory\_Certificate/Real-World-Testing-Results</a> 2023 Regulatory.pdf

### [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]	<b>Reason</b> [Describe the reason this change occurred]	<b>Impact</b> [Describe what impact this change had on the execution of your Real World Testing activities]
No Changes Done	N/A	N/A

## [OPTIONAL] WITHDRAWN PRODUCTS

SINC HealthIT CERTIFICATION PROGRAM

If a developer withdrew any products within the past year that were previously included in their Real World Testing plan, please provide the following information.

Product Name(s):	BI-Clinical
Version Number(s):	BIC 2021
CHPL Product Number(s):	15.04.04.2694.BICL.21.07.0.201020
Date(s) Withdrawn:	Dec-2022
Inclusion of Data in Results Report: [Provide a statement as to whether any data was captured on the withdrawn products. If so, this data should be identified in the results report.]	No data was captured on the withdrawn product during the mentioned measurement year.

Product Name(s):	BI-Clinical
Version Number(s):	2022
CHPL Product Number(s):	15.04.04.2694.BICL.22.08.0.211116
Date(s) Withdrawn:	Dec-2023
Inclusion of Data in Results Report: [Provide a statement as to whether any data was captured on the withdrawn products. If so, this data should be identified in the results report.]	No data was captured on the withdrawn product during the mentioned measurement year.

### SUMMARY OF TESTING METHODS AND KEY FINDINGS

Provide a summary of the Real World Testing methods deployed to demonstrate real-world interoperability, including any challenges or lessons learned from the chosen approach. Summarize how the results that will be shared in this report demonstrate real-world interoperability.

If any non-conformities were discovered and reported to the ONC-ACB during testing, outline these incidences and how they were addressed.

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

Multifacility Hospital system and General Acute care and critical access hospital care setting was tested during this certification.

Successfully generated QRDA Category III files using Perform+, this integration demonstrates the seamless functionality of our system, allowing clients to efficiently generate and submit eCQMs to CMS.

## STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) AND UNITED STATES CORE DATA FOR INTEROPERABILITY (USCDI))

Both required and voluntary standards updates must be addressed in the Real World Testing plan. Real World Testing plans must include all certified health IT updated to newer versions of standards prior to August 31 of the year in which the updates were made.

Indicate as to whether optional standards, via SVAP and/or USCDI, are leveraged as part of the certification of your health IT product(s).

[ ] Yes, I have products certified with voluntary SVAP or USCDI standards. (If yes, please complete the table below.

Standard (and version)	
Updated certification criteria and associated product	
CHPL Product Number	
Conformance measure	

[ $\checkmark$ ] No, none of my products include these voluntary standards.

#### Care Setting(s)

The expectation is that a developer's Real World Testing is conducted within each type of clinical setting in which their certified health IT is marketed. Health IT developers are not required to test their certified health IT in every setting in which it is marketed for use.

List each care setting that was tested.

**NC** Healthl

Multi-facility Hospital system and General Acute care and critical access hospital care

#### Metrics and Outcomes

Health IT developers should detail outcomes from their testing that 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.

Health IT developers could also detail outcomes that did <u>not</u> result from their measurement approach if that better describes their efforts.

Within this section, health IT developers should also describe how the specific data collected from their Real World Testing measures demonstrate their results. Where possible, context should be provided to the measures and results to understand the number of sites/users/transactions tested for the specified measures (i.e., the denominator for comparison to the reported results). If applicable, any Relied Upon Software that is used to meet a criterion's requirements should be included in this section.

Associated Criterion(a)	Relied Upon Software (if applicable)	Outcomes	Challenges Encountered (if applicable)
'§770.315(c) (2-3)-clinical quality measures (CQMs)' §170.315(c)(2)- Import and calculate		<ul> <li>Exported CQMs contain data as expected</li> <li>QRDA files are able to be imported and calculations run as expected</li> <li>QRDA I and QRDA III are generated correctly</li> <li>It is compliant with the certification criteria, including the required technical standards and vocabulary codes sets.</li> <li>A successful measure submission indicates compliance to the underlying ONC criteria</li> <li>For EH 2024 measures:</li> <li>Number of measures recorded during the period: 15</li> <li>Number of QRDA Category 1 files exported: 141</li> <li>Number of QRDA category 1 files imported (if applicable)- 141</li> <li>Number of QRDA Category 3 aggregate report(s) created over the period: 141</li> <li>For EP 2024 measures:</li> <li>Number of measures recorded during the period: 11</li> <li>Number of QRDA Category 1</li> </ul>	
	Criterion(a) '§770.315(c) (2-3)-clinical quality measures (CQMs)' §170.315(c)(2)- Import and	Criterion(a)Software (if applicable)'§770.315(c) (2-3)-clinical quality measures (CQMs)'	Criterion(a)Software (if applicable)Outcomes'§770.315(c) (2-3)-clinical quality measures (CQMs)'• Exported CQMs contain data as expected • QRDA files are able to be imported and calculations run as expected • QRDA 1 and QRDA III are generated correctly • It is compliant with the certification criteria, including the required technical standards and vocabulary codes sets. • A successful measure submission indicates compliance to the underlying ONC criteriaFor EH 2024 measures: • Number of QRDA Category 1 files imported (if applicable)- 141 • Number of QRDA Category 3 aggregate report(s) created over the period: 141For EP 2024 measures: • Number of measures recorded during the period: 141

	<ul> <li>Number of QRDA category 1 files imported (if applicable)- 79</li> <li>Number of QRDA Category 3 aggregate report(s) created over the period: 79</li> </ul>	

#### **KEY MILESTONES**

Include a list of key milestones that were met during the Real World Testing process. Include details on how and when the developer implemented measures and collected data. Key milestones should be relevant and directly related to outcomes discussed.

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

Key Milestone	Care Setting	Date/Timeframe
Certified eCQM measures/ Inpatient clinical quality measure	Inpatient care Setting	Nov 2021
Certified eCQM measures/ Inpatient clinical quality measure	Inpatient care Setting	Oct 2020
2022 Real World Testing Results report creation and submission to ACB	Inpatient care Setting	Feb 2023
Certified eCQM measures/ Inpatient clinical quality measure	Inpatient care Setting	November 7 <sup>th</sup> 2023
Follow-up with providers and authorized representatives on a regular basis to understand any issues arising with the data Submission.	Inpatient care Setting	March 31st 2024
During the last quarter of year 2023, the CY 2024 Real world test plan will be completed according to the ONC and the ONC-ACB requirements and expectations. Test plan will be prepared for submission before the end of the year.	Inpatient (Multifacility Hospital system and General Acute care and critical access hospital care)	Nov 2023



If any non-compliance is observed, we will notify the ONC- ACB of the findings and make the necessary changes as required.	Inpatient care Setting	April – June 2023
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