REAL WORLD TESTING RESULTS REPORT TEMPLATE

BACKGROUND & INSTRUCTIONS

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.

A Real World Testing plan template 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, 85 FR 25642 (May 1, 2020) (**ONC Cures Act Final Rule**)
    - Section VII.B.5 — *"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): PulseCheck ED

Version Number(s): 6.0, 7.0

Certified Health IT Product List (CHPL) Product Number(s): 15.02.04.3070.Puls.06.02.1.211216
15.02.04.3070.Puls.07.03.1.211216

Developer Real World Testing Plan Page URL: https://pulsechecked.com/onc-certified/

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]
No 5.7.1 data included	No erx clients on 5.7.1 in 2022	None as erx functionality was unchanged between versions

[OPTIONAL] WITHDRAWN PRODUCTS

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):	
Version Number(s):	
CHPL Product Number(s):	
Date(s) Withdrawn:	
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.]	

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.

Real World Testing Measure #1: Success rate of eRx messages over pertinent timeframe

Associated certification criteria: §170.315(b)(3) Electronic prescribing

Electronic prescriptions were captured and errors identified for 1 year period for 3 clients representing 3 supported drug databases.

Real World Testing Measure #2 Number of transmissions to public health agency (syndromic surveillance) messages created

Associated certification criteria: §170.315(f)(2) Transmission to public health agencies — syndromic surveillance

Syndromic surveillance messages were captured and counted for a 6 month period for 1 client.

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).

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

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

Standard (and version)	NCPDP Script
Updated certification criteria and associated product	§ 170.315(b)(3)
CHPL Product Number	15.02.04.3070.Puls.06.02.1.211216 15.02.04.3070.Puls.07.03.1.211216
Conformance measure	NCPDP Script Implementation Guide version 2017071

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.

PulseCheck ED is an emergency department electronic medical record (ED EMR) that supports deployment and tracking of features used within the Emergency Department setting.

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.

(from 85 FR 25766)

Health IT developers could also detail outcomes that did not 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.

Measurement /Metric	Associated Criterion(a)	Relied Upon Software (if applicable)	Outcomes	Challenges Encountered (if applicable)
Success Rate of eRx Messages	§170.315(b)(3) Electronic prescribing	Dr First Rcopia	95856 (not error or failure) / 99071 (total electronic prescriptions) =96.75% success rate	
Number of syndromic surveillance messages created	§170.315(f)(2) Transmission to public health agencies — syndromic surveillance	HSF	73663 total messages	

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
Develop candidate list of clients to assist with the Real World Testing	Emergency Dept	Q1 2024
Begin data collection period	Emergency Dept	Q1 2024
End of Real World Testing period/final collection of all data for analysis	Emergency Dept	Dec 2024

Analysis and report creation	Emergency Dept	Jan 2025
Submit Real World Testing report to ACB	Emergency Dept	Jan 2025