Health IT Certification Program

The Office of the National Coordinator for Health Information Technology

REAL WORLD TESTING PLAN

BACKGROUND & INSTRUCTIONS

Under the ONC Health IT Certification Program (**Program**), Health IT Developers are required to conduct Real World Testing of their Certified Health IT (45 CFR 170.556 and 170.523(i)). 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 to develop their Real World Testing plans.

Health IT Developers have maximum flexibility to develop innovative plans and measures for Real World Testing. As developers are planning for how they will execute Real World Testing, they should consider the overall complexity of the workflows and use cases within the care settings in which they market their Certified Health IT to determine which approaches they will take. This 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. Health IT Developers must submit one plan for each year of Real World Testing (see resources listed below for specific timelines and due dates). ONC does not encourage updating plans outside the submission timeline and will not post updates on the Certified Health IT Product List (CHPL). 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 would expect that the Real World Testing results report will include a description of these types of changes, the reasons for them, and how intended outcomes were more efficiently met as a result. This resource should be read and understood in conjunction with the following companion resources, which describe in detail many of the 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 Program.

- 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program final rule, [85 FR 25642](#) (May 1, 2020) (**Century Cures final rule**)
  - ↪ *[Section VII.B.5](#) — "Real World Testing"*

GENERAL INFORMATION

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

Developer Name: Exym

Product Name(s): Exym

Version Number(s): 1.0

Certified Health IT Product List (CHPL) ID(s): 15.04.04.3109.Exym.01.00.0.220513

Developer Real World Testing Page URL: https://exym.com/onc-certification-and-meaningful-use/

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

Consistent with the ONC's recommendation that "Real World Testing verify that deployed Certified Health IT continues to ***perform as intended by conducting and measuring observations of interoperability and data exchange***", this test plan focuses on capturing and documenting the number of instances that certified capability is successfully utilized in the real world. In instances where no evidence exists due to zero adoption of a certified capability or the inability to capture evidence of successful use for other reasons, we will demonstrate the required certified capability in a semi-controlled setting as close to a "real world" implementation as possible.

It is important to note that Real World Testing is only one component of the Health IT Certification program used to demonstrate compliance with the program requirements. Real World Testing should augment and support testing that was conducted prior to certification being granted. It is not intended to duplicate the methods or results previously demonstrated. Instead, this test plan was developed to demonstrate that the certified capabilities have been successfully deployed for providers to use at their discretion in live settings.

Exym is a behavioral health EHR system serving mental health and substance abuse patients. While information exchange is crucial, especially for coordinating care with primary care physicians, patients often limit shared data for privacy reasons. Real World Testing of Exym's system will focus on ambulatory behavioral health settings. The test plan will utilize metrics generated by providers' usage of our chart export tools.

Summative assessments will be used to measure which certified actions were performed at the conclusion of a given time period. These will be conducted by generating reports and examining audit logs from within the certified health IT module to help demonstrate the frequency of actions within the given time frame, and where possible, whether those actions were successful or unsuccessful. High success rates should be an indicator of a successful implementation of a given certified capability in a real-world setting.

STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS-SVAP AND 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.

Describe approach(es) for demonstrating conformance to all certification requirements using each standard to which the health IT is certified. List each version of a given standard separately. For each version of a standard submit the following:

- ✓ Identify standard versions
- ✓ Indicate what 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
- ✓ If SVAP, date notification sent to customers
- ✓ 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?

Exym has not updated AWARDS to any new standards as part of SVAP or HTI-1 criteria as of August of this year. We have not yet updated from USCDI v.1.

Standard (and version)	All standards versions are those specified in USCDI v1, HL7 r 2.1
Updated certification criteria and associated product	Exym v.1
CHPL Product Number	15.04.04.3109.Exym.01.00.0.220513
Method used for standard update	N/A
Date of ONC ACB notification	5/13/2022
Date of customer notification (SVAP only)	N/A
Conformance measure	N/A
USCDI updated certification criteria (and USCDI version)	USCDI v1

MEASURES USED IN OVERALL APPROACH

For each measurement/metric, describe the elements below:

- ✓ Description of the measurement/metric
- ✓ Associated certification criteria
- ✓ Care setting(s) that are addressed
- ✓ Justification for selected measurement/metric
- ✓ Expected Outcomes

Description of Measurement/Metric

Describe the measure(s) that will be used to support the overall approach to Real World Testing.

Measurement/Metric	Description
Number of active customers (practices) and users in Exym	Identify the number of customers (practices) and users that utilize Exym, in the past 90 days prior to RWT report creation.
Number of customers and users accessing single patient chart export	Identify the total number of instances that customers and users have executed a single client chart export via self-service in the past 90 days prior to RWT report creation.

Associated Certification Criteria

List certification criteria associated with the measure and if updated to the 2015 Edition Cures Update criteria. If conformance to the criteria depends on any Relied Upon Software, this should be noted in your Real World Testing plan for any metrics that would involve use of that software in testing.

Measurement/Metric	Associated Certification Criteria	Relied Upon Software
Individual Chart Export Creation Count	170.315 (b)(10)	N/A
Bulk Client Chart Export Count	170.315 (b)(10)	N/A

Justification for Selected Measurement/Metric

Provide an explanation for the measurement/metric selected to conduct Real World Testing.

Measurement/Metric	Justification
Individual Chart Export Creation Count	These metrics are easily reportable by simple queries and provides insight on chart export took usage and frequency of errors.
Bulk Client Chart Export Count	When Bulk Client Chart Export requests occur, we will monitor the duration it takes to complete a CCD bulk export with no errors.

Care Setting(s)

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. Health IT developers are not required to test their certified health IT in every setting in which it is marketed for use. Developers should address their choice of care and/or practice settings to test and provide a justification for the chosen approach.

Note: 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

List each care setting which is covered by the measure and an explanation for why it is included.

Care Setting	Justification
Ambulatory Behavioral Health	Exym is a behavioral health EHR system and only services mental health and substance use patients.

Expected Outcomes

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.

(from 85 FR 25766)

Not all of the expected outcomes listed above will be applicable to every certified Health IT Module, and health IT developers may add an additional description of how their measurement approach best addresses the ongoing interoperability functionality of their product(s). Health IT developers could also detail outcomes that should 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 expected results. Expected outcomes and specific measures do not necessarily have to include performance targets or benchmarks, but health IT 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.

Measurement/Metric	Expected Outcomes
Single Chart Export Generation from user self service	Over a 90 day period, count of all the single client chart exports performed.
Delivery of bulk chart export delivery to customer (practice) when requested.	Over a 90 day period, count of bulk client chart exports for identified patient population to demonstrate available capability is effective and available.

SCHEDULE OF KEY MILESTONES

Include steps within the Real World Testing plan that establish milestones within the process. Include details on how and when the developer will implement measures and collect data. Key milestones should be relevant and directly related to expected outcomes discussed in the next section.

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

Key Milestone	Care Setting	Date/Timeframe
Data Collection	Ambulatory Behavioral Health	Jan 2026
Analyze Data	Ambulatory Behavioral Health	Jan 2026
Data Reporting	Ambulatory Behavioral Health	Jan 2026

ATTESTATION

This Real World Testing plan is complete with all required elements, including measures that address all certification criteria and care settings. All information in this plan is up to date and fully addresses the Health IT Developer's Real World Testing requirements.

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