REAL WORLD TESTING PLAN TEMPLATE

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 170.405). 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.

Health IT developers have maximum flexibility to develop innovative plans and measures for Real World Testing. As developers are planning 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 the 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. While the use of this template is voluntary, health IT developers may find it useful in preparing their Real-World Testing plans. 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 expects 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. **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 Program requirements referenced in this resource.**

- Real World Testing–What It Means for Health IT Developers – Fact Sheet
- Real World Testing Resource Guide – Coming Soon
- 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) (**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 plan. 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. These fields serve as a foundation of information

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: Netsmart

Product Name(s): gEHRiMed

Version Number(s): 4.0, 4.1, 4.2

Certified Health IT: 170.315(b)(1), 170.315(b)(2), 170.315(b)(6), 170.315(e)(1), 170.315(f)(1), 170.315(b)(2), 170.315(g)(7), 170.315(g)(8), 170.315(g)(9)

Product List (CHPL) ID(s): 15.04.04.1532.gEHR.04.02.1.210420

Developer Real World Testing Page URL: https://www.ntst.com/-/media/pdfs/certifications/gmd-rwt-public-health.pdf

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.

Use Case: Evaluating real-world use of Public Health – Transmission to immunization registries, and Transmission to public health agencies – syndromic surveillance. Evaluating real-world use of transmission to immunization registries, and syndromic surveillance, we find that none of our clients are using this functionality in the real-world setting. As such, after consulting with our ONC-ACB, we will be using test data in a live / mirrored production environment to evaluate real world applicability of creating immunization information according to referenced standards, and allowing users to access, access, and display this information. In addition, we will evaluate syndrome-based public health surveillance information according to standards referenced. 170.315(f)(1): Transmission to immunization registries

170.315(f)(2): Transmission to immunization registries – syndromic surveillance

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.

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 ID 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?*

Standard (and version)	§170.315 (f)(1) *Transmission to immunization registries*—
	Paragraph (f)(1)(i) § 170.205(e)(4) HL7 2.5.1 *Implementation Specifications*. HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5, October 2014 and HL7 Version 2.5.1 Implementation Guide for Immunization Messaging (Release 1.5)—Addendum, July 2015 § 170.207(e)(3) HL7 Standard Code Set CVX— Vaccines Administered, updates through August 17, 2015 § 170.207(e)(4) National Drug Code (NDC) Directory– Vaccine NDC Linker, updates through August 17, 2015
	Paragraph (f)(1)(ii) § 170.205(e)(4) HL7 2.5.1 *Implementation Specifications*. HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5, October

	2014 and HL7 Version 2.5.1 Implementation Guide for Immunization Messaging (Release 1.5)—Addendum, July 2015 §170.315 (f)(2) *Transmission to public health agencies – syndromic surveillance—* Applies to entire criterion § 170.205(d)(4) HL7 2.5.1. *Implementation specifications*. PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent, Care, Inpatient and Ambulatory Care, and Inpatient Settings, Release 2.0, April 21, 2015 and Erratum to the CDC PHIN 2.0 Implementation Guide, August 2015
Updated certification criteria and associated product	No updates have been made.
Health IT Module CHPL ID	15.04.04.1532.gEHR.04.02.1.210420
Method used for standard update	N/A, updates have not been made
Date of ONC-ACB notification	04/20/2021
Date of customer notification (SVAP only)	n/a
Conformance measure	n/a
USCDI-updated certification criteria (and USCDI version)	n/a

MEASURES USED IN OVERALL APPROACH

Each plan must include at least one measurement/metric that addresses each applicable certification criterion in the Health IT Module's scope of certification. Describe the method for measuring how the approach(es) chosen meet the intent and purpose of Real-World Testing.

For each measurement/metric, describe the elements below:

- ✓ Description of the measurement/metric
- ✓ Associated certification criteria
- ✓ Justification for selected measurement/metric
- ✓ Care setting(s) that is addressed
- ✓ 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
170.315(f)(1): Transmission to immunization registries Number of HL7 transmissions sent for a % population over a time period. Numerator: Total number of test transmissions sent; Denominator: Total population.	Transmission to immunization registries. Using a real-world environment, we will evaluate the transmission of immunization data to immunization registries. We will test the send of the document that would be sent to a registry by evaluating the HL7 document send to a targeted folder.
170.315(f)(2): Syndromic Surveillance. Numerator: Number of test syndromic surveillance submissions sent. Denominator: care population.	Syndromic surveillance: We will evaluate selecting syndromic data and submitting syndromic data for a target numerator population (sending) over the evaluated population. We will test the send of the document that would be sent to a registry by evaluating the HL7 document send to a targeted folder.

ASSOCIATED CERTIFICATION CRITERIA

List certification criteria associated with the measure and if updated to the 2015 Edition Cures Update criteria.

Measurement/Metric	Associated Certification Criteria
170.315(f)(1): Transmission to immunization registries	(i) Create immunization information in accordance with (A) The standard and applicable implementation specifications specified in §170.205(e)(4). (B) At a minimum, the version of the standard specified in §170.207(e)(3) for historical vaccines. (C) At a minimum, the version of the standard specified in §170.207(e) . . (4) for administered vaccines. (ii) Enable a user to request, access, and display a patient's evaluated immunization history and the immunization forecast from an immunization registry in accordance with the standard at §170.205(e)(4).
170.315 (f)(2) Syndromic Surveillance	Create syndrome-based public health surveillance information for electronic transmission in accordance with the standard (and applicable implementation specifications) specified in §170.205(d)(4).

JUSTIFICATION FOR SELECTED MEASUREMENT/METRIC

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

Measurement/Metric	Justification
170.315(f)(1): Transmission to immunization registries Number of HL7 transmissions sent for a % population over a time period. Numerator: Total number of Transmission sent; Denominator: Total population.	This metric allows testing of how transmission to immunization registries functions in the real-world setting. Because no clients use this functionality in the real-world setting, currently, we'll be using test data in a real-world environment. We will evaluate transmission of immunization data and the results thereof. As we have no clients using this functionality, we are currently not partnered with an immunization registry. After clarifying with our ONC-ACB, we will be testing the HL7 file(s) generated and sent to a target folder, in the same fashion that would be sent to a registry.
170.315(f)(2): Syndromic Surveillance. Numerator: Number of syndromic surveillance submissions sent. Denominator: care population.	This metric allows testing of how syndromic surveillance functions in a real-world scenario. As we have no clients using this certified functionality, we will be using test data in a real world setting to create syndrome based public health information. As we have no clients using this functionality, we are currently not partnered with a syndromic surveillance registry. After clarifying with our ONC-ACB, we will be testing the HL7 file(s) generated and sent to a target folder, in the same fashion that would be sent to a registry.

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
The user population for this functionality is in a post-acute, long term care setting.	This is the care setting in which Gehrimed electronic health record technology is used.

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
170.315(f)(1): Transmission to immunization registries Number of HL7 transmissions sent for a % population over a time period. Numerator: Total number of Transmission sent; Denominator: Total population.	Expected validation of normal sending immunization data in our test environment per the associated standards referenced in the regulation. Per the standards and related regulations, we will be sending test files via compliant HL7 format.
170.315(f)(2): Syndromic Surveillance. Numerator: Number of syndromic surveillance submissions sent. Denominator: care population.	Expected validation of normal sending syndromic data in our test environment per the associated standards referenced in the regulation. Per the standards and related regulations, we will be sending test files via compliant HL7 format.

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
Creation of test environment	Long Term Post-Acute Care	1/30/2022
Set up of evaluation of immunization send / validation on a repeating schedule	Long Term Post-Acute Care	2/15/2022
Over a timeframe specified: analyze data sent	Long Term Post-Acute Care	2/15/2022-EOY

ATTESTATION

The Real-World Testing plan must include the following attestation signed by the health IT developer authorized representative.

Note: The plan must be approved by a health IT developer authorized representative capable of binding the health IT developer for execution of the plan and include the representative's contact information.[ii]

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.

Authorized Representative Name: Benjamin Britton

Authorized Representative Email: bbritton@ntst.com

Authorized Representative Phone: 970-658-6897

Authorized Representative Signature:

Date: 9/29/2021

[i] Certified health IT continues to be compliant with the certification criteria, including the required technical standards and vocabulary codes sets; certified health IT is exchanging EHI in the care and practice settings for which it is marketed for use; and EHI is received by and used in the certified health IT. (85 FR 25766)

[ii] https://www.federalregister.gov/d/2020-07419/p-3582