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: VigiLanz Corporation

Product Name(s): Dynamic Antimicrobial Steward

Version Number(s): 2017

Certified Health IT Product List (CHPL) ID(s): 15.04.04.2953.Dyna.17.00.0.170216

Developer Real World Testing Page URL: N/A

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.

The goal of the real world testing is to measure the successful creation and transmission of properly formatted CDA files for AUR reporting to CDC/NHSN. In this effort, VigiLanz will measure the number of client-generated submission requests, number of submissions sent and number of responses received. VigiLanz has log data that will be used to quantify AUR files generated, DIRECT messages sent via secure HISP and any acknowledgements received from the NHSN system (which is not guaranteed). VigiLanz has no access to error information related to submissions that is provided to clients through the NHSN portal. This information must come from client partners. Identifying client partners is an initial step of the RWT plan.

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)	N/A
Updated certification criteria and associated product	N/A
Health IT Module CHPL ID	N/A
Method used for standard update	N/A
Date of ONC ACB notification	N/A
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
Submission requests	Count of client requests to generate AUR (AU and AR) files and submit to NHSN. This data is captured in system logs.
Submissions sent	Count of DIRECT submissions of AUR data to NHSN. This data is captured in system logs.
Responses received	Count of responses received from NHSN for AUR submissions. This data is captured in system logs.
Client-reported errors	Count of errors observed by client (not available to VigiLanz otherwise). This data must be provided by clients partnering in the RWT process.

All counts will be used for tracking and trending over time. Data collected in the first year will serve as a baseline.

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
Submission requests	§ 170.315(f)(6) - Transmission to public health agencies — antimicrobial use and resistance reporting
Submissions sent	§ 170.315(f)(6) - Transmission to public health agencies — antimicrobial use and resistance reporting
Responses received	§ 170.315(f)(6) - Transmission to public health agencies — antimicrobial use and resistance reporting

Justification for Selected Measurement/Metric

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

Direct submission of AUR data is a client-driven, asynchronous process. The underlying transmission method (DIRECT HISP) is email and does not provide confirmation of sent messages. The receiving system (NHSN) sends responses that are largely dependent on the volume of data, which can range from minutes to days. Clients will be selected to partner with VigiLanz throughout the testing period and will be sent quarterly questionnaires regarding AUR activity. VigiLanz will establish start and end dates that define the data collection timeframe.

Measurement/Metric	Justification
Submission requests	The submission requests are an indicator that users have initiated the process of transmitting AUR data to the NHSN. This is an indication that the AUR data generation process is functioning.
Submissions sent	This is an indicator that the DIRECT transmission process is working as intended.
Responses received	This is an indicator that the DIRECT transmission was received by NHSN. It is also an indicator of data interoperability via properly formatted CDA files.
Client-reported errors	VigiLanz has no access to success/failure information in the client's NHSN portal. Any errors observed by the client must be communicated to VigiLanz.

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
Inpatient facilities	VigiLanz' clients are inpatient facilities. Inpatient facilities can participate in the AUR (AU and AR) portion of the NHSN patient safety program.

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
Submission requests	Successful creation of all required AUR files: AU numerator, AR Events (numerator) and AR Denominator.
Submissions sent	Successful transmission from the VigiLanz HISP.
Responses received	Response from NHSN, indicating transmission was received and files were ingested.
Client-reported errors	NHSN notifies clients of configuration and other correctable errors. Client will report other errors to VigiLanz for investigation.

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
Identify clients who will partner with VigiLanz for the Real World Testing	Inpatient facilities	December 2021 – January 2022
Collect data for AUR requests, submissions and responses	Inpatient facilities	Monthly 2022
Contact clients to collect AUR activity data	Inpatient facilities	Quarterly 2022
Data collection period ends	Inpatient facilities	December 2022
Compile and analyze data. Produce RWT report	Inpatient facilities	January 2023
Submit RWT report	Inpatient facilities	February 2023

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:	Craig Leischner
Authorized Representative Email:	cleischner@vigilanzcorp.com
Authorized Representative Phone:	855.525.9078 x402
Authorized Representative Signature:	
Date:	November 12, 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