REAL WORLD TESTING PLAN 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.

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
- 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"
- Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Final Rule, 89 FR 1192 (March 11, 2024) (**HTI-1 Final Rule**)
  - Section III.E — "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: Wolters Kluwer

Product Name(s): Sentri7 & Sentri7 AUR Reporting

Version Number(s): 2023

Certified Health IT Product List (CHPL) ID(s):

15.04.04.3136.sent.23.00.0.221223 ; 15.04.04.3136.sent.23.00.0.230526

Developer Real World Testing Plan Page URL:
https://www.wolterskluwer.com/en/solutions/solesource/realworld-testing-plan-and-results

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 objective of 170.315(f)(6) is electronic transmission of Antimicrobial Use and Resistance (AUR) data to NHSN. Our testing approach will evaluate this objective by providing a de-duplicated count of the number of successful and failed submissions for each AUR document type in a monthly reporting period for Sentri7 customers who report AUR data to NHSN.

STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) STANDARDS UPDATES

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

Date notification sent to ONC-ACB *Date notification sent to customers*

Method used to demonstrate conformance with updated standard(s) *Measurement(s)/metric(s) associated with Real World Testing*

Standard (and version)	(f)(6) AU & AR reporting & (b)(10) EHI Export
Updated certification criteria and associated product	(f)(6) AU & AR Reporting & (b)(10) EHI Export
Health IT Module CHPL ID	15.04.04.3136.Sent.23.00.0.221223; 15.04.04.3136.Sent.23.00.0.230526
Date of ONC ACB notification	N/A

Date of customer notification	N/A
Conformance method and measurement/metric(s)	(f)(6) Records Successfully sent to NHSN (b)(10) Electronic Health Record Export from Sentri7

MEASUREMENT(S)/METRIC(S) 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 measurement(s)/metric(s) that will be used to support the overall approach to Real World Testing.

Measurement/Metric	Description
(f)(6) AR and AU submissions to NHSN	Monthly count of successful & failed AR num and denom and AU summary submissions to NHSN
(b)(10) Electronic Health Information Export	Annual count of successful & failed real time requests for a patient health records export by a Sentri7 administrators

Associated Certification Criteria

List certification criteria associated with the measurement/metric. 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 (if applicable)

(f)(6) AR and AU submissions to NHSN	170.315(f)(6)	N/A
(b)(10) Electronic Health Information Export	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
(f)(6) AR and AU submissions to NHSN	Monthly success/failure rate of submissions demonstrates ongoing interoperability
(b)(10) electronic Health Information Export	Annual success/fail real time requests for a patient health records export by a Sentri7 administrators to demonstrate real time export without developer interventions

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
(f)(6): NHSN-defined inpatient locations and select outpatient acute care settings	Care settings considered for NHSN AUR submission are specified in the NHSN AUR protocol (https://www.cdc.gov/nhsn/pdfs/pscmanual/11pscaurcurrent.pdf)
(b)(10) NHSN – defined inpatient locations	Admins with EHI export permissions in Sentri7 can export a full health record for a specific or batch of 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
(f)(6) AR and AU submissions to NHSN	NHSN accepts Sentri7's AUR submissions that comply with the AUR protocol
(b)(10) Criteria Electronic Health Information Export	A 100% successful export rate for on demand patient health record export for sentri7 Admins, without the intervention of a developer. On-Demand Patient Data Access: Sentri7 AUR allows for customers to export health information for patients and other users at any time without requiring developer assistance. A publicly accessible hyperlink of the export's format: The exported files are required to be in an electronic and computable format accessible through a public and up-to-date hyperlink to ensure authorized users can retrieve information straight away. User Authorization Control: To effectively safeguard patient data from unauthorized use and support secure and controlled access to EHI exports, Sentri7 AUR limits users authorized for EHI exports to Admins only.

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
Analysis & Report Creation/Submission	N/A	December 30th 2025
Submit & publish RWT results	N/A	January 30th 2026

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

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: Marina Zaki

Authorized Representative Email: marina.zaki@wolterskluwer.com

Authorized Representative Phone: 919-600-1466

Authorized Representative Signature: Marina Zaki

Date: 10/8/2024

[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