

REAL WORLD TESTING PLAN TEMPLATE

GENERAL INFORMATION

Plan Report ID Number	[For ONC-Authorized Certification Body use only]
Developer Name	Indiana Health Information Exchange
Product Name(s)	Notifiable Condition Detector (NCD)
Version Number(s)	2.1
Certified Health IT Product List (CHPL) ID(s)	15.07.05.1674.IHIE.01.00.1.230330
Developer Real World Testing Plan Page URL	https://www.ihie.org/real-world-testing/

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.ⁱⁱ

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.

- Multiple days' worth of messages will be sent through the NCD. Conditions that are deemed reportable by IAC-410 (Indiana Administrative Code 410) to be flagged. NCD has one client and that is the Indiana Department of Health (IDOH). Counts by condition can be shared to show successful identification/processing.

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)	No standards update
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
- ✓ Relied upon software
- ✓ 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
Count of Conditions flagged by NCD	Count by condition - Anything flagged by NCD

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 (if applicable)
Count of Conditions flagged by NCD	170.315(f)(3) Transmission to public health agencies -- reportable laboratory tests and value/results	

Justification for Selected Measurement/Metric

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

Measurement/Metric	Justification
Count of Conditions flagged by NCD	Testing to prove successful transmission of laboratory-reportable findings to appropriate local, state, territorial and federal health agencies using the message

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
Indiana Department of Health (IDOH)	Results from the NCD are sent to the epidemiologists with the IDOH. Our testing would include adding a count mechanism to provide counts by reportable condition flagged.

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
Count of Conditions flagged by NCD	<p>The intake of Electronic Lab Result data from IHIE-connected hospitals will go through an enhancement process within NCD that will produce “reportable results” of lab data on a particular patient for a reportable condition tracked by NCD (e.g., Measles). For real-world testing, we will aggregate reportable results out of NCD and document the count of observable results for each condition listed for the specified period. A condition will be successfully flagged if the ELR data triggers a corresponding condition using an existing LOINC (Logical Observation Identifiers Names and Codes) code within NCD.</p> <p>If there is a discrepancy or unexpected volume of reportable results for a particular condition based on IDOH findings, a workflow is triggered for diagnosing the issue. This typically includes troubleshooting improperly formatted HL7 data sent by the hospital, or a missing LOINC code for a condition that will then be added to NCD’s database by IHIE. There is ongoing communication and bi-weekly discussions between IHIE and the IDOH to address support issues and maintenance requests pertaining to NCD and ELR data.</p>

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
Scheduling with IDOH, identifying resources on their side to assist with the testing	IDOH	2 days (Q1 2024)
Flagging and delivering reportable lab results	IDOH	1 business week (Q1 2024)
Daily reporting of forementioned flag results in email format by condition and location transmitted to the IDOH	IDOH	1 business week (Q1 2024)

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.

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Authorized Representative Signature	Jonathon J. Showalter
Date	10/19/23

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>