

# REAL WORLD TESTING PLAN

## 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”

## GENERAL INFORMATION

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

Developer Name: **Imprivata**

Product Name(s): **Digital Identity Intelligence, Imprivata FairWarning**

Version Number(s): **24, 23**

Certified Health IT Product List (CHPL) ID(s): **15.02.05.1485.DIGI.07.07.0.240213,  
15.02.05.1485.FAIR.06.06.0.230130**

Developer Real World Testing Plan Page URL: **<https://www.imprivata.com/onc-certification-disclosures>**

## 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..<sup>1</sup>*

*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.*

Digital Identity Intelligence helps safeguard against inappropriate access to medical records, protect the privacy of patient data, and prevent violations by monitoring and auditing internal access. These capabilities aid in the creation of a culture of privacy, while also supporting risk reduction. Our solution provides health systems with the ability to manage the entire process from alerts to investigations, while reducing risk and improving compliance by enabling more precise and easier to audit user access data across a broader set of enterprise applications. Digital Identity Intelligence is a health IT which supports the ability to export electronic health information (EHI) in an electronic and computable format. The Real World Testing plan was designed to show Imprivata's continued efforts to conform to the below listed criteria.

## 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
Export functionality	Assess application ability to export EHI for a single patient in a production environment

### 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.

Certification Criteria	Requirement
§ 170.315 (b)(10) Electronic Health Information Export	(i) Single patient electronic health information export...
	(ii) Patient population electronic health information export...
	(iii) Documentation...

### Justification for Selected Measurement/Metric

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

Measurement/Metric	Justification
Export functionality	Demonstrate the utility of the health information export functionality

**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
Export functionality	Only users with the permissions for export capabilities, can do so from the Report Results page in CSV (Comma Separated Value) format and data fields included in the export capabilities are configurable by end users.

## 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	Date/Timeframe
Execute testing plans (done monthly with our QA cycle)	January 2024 to January 2025
Analysis of results	On-going 2024
Submit Real World Testing results to ACB	February 2025

## 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.<sup>ii</sup>

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: Matt Carlson

Authorized Representative Email: matt.carlson@imprivata.com

Authorized Representative Phone: 727-576-6700

Authorized Representative Signature: *Matt Carlson*

Date: 10/15/2024

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<sup>i</sup> 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)

<sup>ii</sup> <https://www.federalregister.gov/d/2020-07419/p-3582>