

# REAL WORLD TESTING PLAN

## GENERAL INFORMATION

Plan Report ID Number: 20241206ia6

Developer Name: Iatric Systems, Inc

Product Name(s): Haystack iS

Version Number(s): 1.0

Certified Health IT Product List (CHPL) ID(s): 15.05.05.2760.HSiS.01.00.0.210426

Developer Real World Testing Plan Page URL: <https://new.iatric.com/real-world-testing>

## JUSTIFICATION FOR REAL WORLD TESTING APPROACH

Haystack iS is certified health IT software which stores limited electronic health information (EHI) supports the ability to export EHI in an electronic and computable format. Haystack iS is not patient care-centered software and accessible by hospital staff/users as determined by the customer.

170.315(b) (10) Electronic Health Information Export

The applications provide the export of electronic health information (EHI) for a single patient as well as for a patient population in the following formats

## STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) STANDARDS UPDATES

Haystack iS product does not include voluntary SVAP standards updates.

## MEASUREMENT(S)/METRIC(S) USED IN OVERALL APPROACH

### Description of Measurement/Metric

Measurement/Metric	Description
§ 170.315 (b)(10) <i>Electronic Health Information export-</i>	<ol style="list-style-type: none"> <li>1. <i>Single patient electronic health information export.</i> <ol style="list-style-type: none"> <li>1. Enable a user to timely create an export file(s) with all of a single patient’s electronic health information that can be stored at the time of certification by the product, of which the Health IT Module is a part.</li> <li>2. A user must be able to execute this capability at any time the user chooses and without subsequent developer assistance to operate.</li> </ol> </li> </ol>

3. Limit the ability of users who can create such export file(s) in at least one of these two ways:
  1. To a specific set of identified users
  2. As system administrator function.
4. The export file(s) created must be electronic and in a computable format.
5. The publicly accessible hyperlink of the export's format must be included with the exported file(s).
2. *Patient population electronic health information export.* Create an export of all the electronic health information that can be stored at the time of certification by the product, of which the Health IT Module is a part.
  1. The export created must be electronic and in a computable format.
  2. The publicly accessible hyperlink of the export's format must be included with the exported file(s).
3. *Documentation.* The export format(s) used to support paragraphs (b)(10)(i) and (ii) of this section must be kept up to date.

**Associated Certification Criteria**

Measurement/Metric	Associated Certification Criteria	Relied Upon Software (if applicable)
170.315(b) (10) Electronic Health Information Export	170.315(b) (10) Electronic Health Information Export	None

**Justification for Selected Measurement/Metric**

Measurement/Metric	Justification
170.315(b) (10) Electronic Health Information Export	This measure will assess the ability to export the limited data stored by the software by end users. This product is not a patient care product or accessed only by designed users as determined by the customer.

**Care Setting(s)**

Care Setting	Justification
Hospital Setting	Certified Health IT Module is supported for use by hospital healthcare settings. For this reason, the Real-World Testing plan will apply to a hospital setting. Criterion 170.315(b)(10) Electronic Health Information Export. This is not a direct patient care product.

**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.

Measurement/Metric	Expected Outcomes
170.315(b) (10) Electronic Health Information Export	<p>Overall expected outcomes will validate conformance to criteria 170.315 (b)(10) – Electronic Health Information export of health data stored in software by end users.</p> <p>System logs will be reviewed for indication of export completion as expected. It is expected that authorized users will be able to share EHI using the export function. Error rates will be tracked and analyzed over time. If errors occur, investigate and document for resolution planning, if needed</p>

## SCHEDULE OF KEY MILESTONES.

Key Milestone	Date/Timeframe	Care Setting
Initial Real-World Testing with current development healthcare facility partner where we have access to their system for testing and potential development using real patient data for real-world setting type testing.	1/15/25-3/31/25 (Q1)	Hospital Setting
Data collection and review as laid out by the plan to include follow-up with hospital partner	3/1/25-8/31/25 (Q2-Q3)	Hospital Setting
End of Real-World Testing Period with Results	January 2026	Hospital Setting
Analysis and Report Creation	January 2026	Hospital Setting
Submit Real World Testing Report to ACB	February 1, 2026*	Hospital Setting
<i>*Timeline may be adjusted based on ACB's RWT Results due date</i>		

## 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: Amy McKee

Authorized Representative Email: amy.mckee@iatric.com

Authorized Representative Phone: (978) 804-4100, x84047

Authorized Representative Signature: *Amy McKee*

Date: 12/6/2025

<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>