REAL WORLD TESTING PLAN

GENERAL INFORMATION

Plan Report ID Number: 20241206ia5

Developer Name: Iatric Systems, Inc

Product Name(s): Electronic Case Reporting

Version Number(s): 1.0

Certified Health IT Product List (CHPL) ID(s): 15.05.05.2760.IECR.01.00.0.221229

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

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

Public Health Reporting Solutions software (health IT module) provides healthcare providers with a method of transmitting electronic case reports to designed public health agencies for review and action. Electronic Case Reporting (eCR) is the automated generation and transmission of case reports from electronic health records (EHRs) to public health agencies (PHAs) for review and action. eCR reduces the burden on healthcare providers to accomplish their reporting requirements to public health and improves the timeliness and completeness of case reports at the local, state, and national levels.

For this reason, the Real-World Testing plan will apply to a hospital setting. Criteria 170.315(f)(5) Transmission to Public Health Agencies – Electronic Case Reporting.

STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) STANDARDS UPDATES

Electronic Case Reporting 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(f)(5) Transmission to Public Health Agencies – Electronic Case Reporting	Consume and maintain a table of trigger codes to determine which encounters may be reportable. Match a patient visit or encounter to the trigger code based on the parameters of the trigger code table. Create a case report for electronic transmission: -Based on a matched trigger -To include: Data classes are expressed in the standards and Common Clinical Data Set. -Encounter diagnoses formatted to expected standards. -Provider information and reason for the visit. -Identifier representing the row and version of the trigger table triggering the case report

Associated Certification Criteria

Measurement/Metric	Associated Certification Criteria	Relied Upon Software (if applicable)
170.315(f)(5) Transmission to Public Health Agencies – Electronic Case Reporting	170.315(f)(5) Transmission to Public Health Agencies – Electronic Case Reporting	NA

Justification for Selected Measurement/Metric

Measurement/Metric	Justification
170.315(f)(5) Transmission to Public Health Agencies – Electronic Case Reporting	In the hospital setting, we chose to focus on aspects of this criterion that would provide the most patient care value in an actual setting. Public health registries can be helpful to patient care, epidemiologists, and the government for identifying disease outbreaks, epidemics, pandemics, and potential monitoring of social disparities. Required per ONC Real World Testing.

Care Setting(s)

Care Setting	Justification
Hospital Setting	Certified Health IT Module is marketed and actively in use by hospital healthcare settings. For this reason, the Real-World Testing plan will apply to a hospital setting. Criteria 170.315(f)(5) Transmission to Public Health Agencies – Electronic Case Reporting.

ASTP

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.

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Measurement/Metric	Expected Outcomes
170.315(f)(5) Transmission to Public Health Agencies – Electronic Case Reporting.	Overall expected outcomes will validate applications conformant to the software's applicable criteria to exchange and transmit patient health data, patient matching to ensure accurate clinical information reconciliation, and create export summary as stipulated by the criterion regulations. Available system logs will be reviewed for indication of completed exchange to designated party as expected. Error rates will be tracked and analyzed over time. If errors occur, investigate and document for resolution planning, if needed.

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
*Timeline may be adjusted based on ACB's RWT Results due date		

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: Amy McKee

Authorized Representative Email: amy.mckee@iatric.com

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

Authorized Representative Signature: *AmyMcKee*

Date: 12/6/2024

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[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