Willowglade Technologies 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.

GENERAL INFORMATION

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

Developer Name: Willowglade Technologies

Product Name(s): Personal Health Navigator

Version Number(s): 6.0

Certified Health IT Product List (CHPL); 15.11.09.3179.PHN0.06.00.1.231222

Product Number(s): Developer Real World Testing Plan Page URL:

https://www.willowgladetechnologies.com/real-world-testing

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.

Associated Criteria	Standards	Standard Update	Date of ONC- ACB	Date of Customer	Conformance Measure	USCDI Version
		Method	Notification	Notification		
170.204e(1)	170.204(a)(2) Web Content Accessibility Guidelines (WCAG) 2.1	Occurred during Initial Testing	N/A - part of initial testing	N/A - part of initial testing	Accessibility Insights for Web Testing Tool.	N/A
170.204e(1), 170.204g(9)	170.205(a)(5) HL7® CDA R2 Implementation Guide	Occurred during Initial Testing	N/A - part of initial testing	N/A - part of initial testing	Compliance of API resource query	V1

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

Real World Testing of the Personal Health Navigator Patient Portal involves audit patient usage of the portal, APIs and the ability to export patient data in the correct format. In the event that APIs, export or other functionality have no usage, we will conduct internal tests to ensure that the functionality is working, as designed, and to meet the relevant certification requirements.

MEASURES USED IN OVERALL APPROACH

Description of Measurement/Metric

Describe the measure(s) that will be used to support the overall approach to Real World Testing.

Measurement/Metric	Description	Justification	
#1 - Testing 170.315(b)(10) 1. EHI Export – Single Patient Export 2. EHI Export – Patient Population Export	Test the ability to export a single patient record. Test the ability to export a patient population with verification that appropriate permissions / security is required.	This criterion requires that the health IT module provides for the export of either a single patient or a patient population by an authorized admin account. Further, the export must be in a compliant electronic and computable format. The defined measurement will evaluate if the EHI export functionality is being used as well as its frequency of use over a selected period of time.	
# 2 - Testing 170.315e(1) 1. Portal invitations 2. Portal Signups 3. Portal Decline Signup	Measurement of the number (and percentage) of patients that have received portal invitations, the number of those patients that started the signup process, the number of patients that completed the signup process and also the number of patients that declined to sign up for the portal.	This criterion requires the ability of a certified Health IT module to provide patients access to a patient portal with the ability to view, download and transmit their health records. Patients will have this functionality available after they have received an invitation and signed up to access the portal. This measure will provide a numeric value to indicate how often this interoperability feature is being used.	
# 3 - Testing 170.315g(10) 1. API access	Tracking compliance of the certified module's functional support of API query of patient data resources.	This measure will provide assurance of compliance to the certified criteria specifically ability to connect to the modules API resources and query patient clinical data through the API. This measure will also query the patient's C-CDA through the API. Because API criteria, 315(g)(7), (g)(9), and (g)(10), all work together in the API functionality of the module, this measurement is used for all three. To avoid disclosing PHI, we will only work with test patients from the actual production environment or an appropriately production-mirrored	

		environment to best evaluate production capabilities available to end users.
# 4 - Testing 170.315g(7), (9), (10) 1. Compliance of API resource query support	Tests the ability to connect to the patient portal API and query patient data through the API.	This criterion requires that the Certified Health IT module provides not only API access, but also this access is in compliance with the API resource query requirements. The measure used will be the quantification of how many clients or other parties are using (or have used) the API. This metric will indicate the adoption and interoperability of our API interface.
# 5 - 170.204e(1) - Accessibility Testing	Leverage Accessibility insights for web testing tool to verify accessibility.	This metric will incorporate the results of the use of an accessibility testing tool. The measure will be a count of any areas that do not meet accessibility requirements.

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.

Metric	Associated Certification Criteria	Relied Upon Software (if applicable)
EHI Export	170.315(b)(10)	Health Samurai Aidbox 15.99.04.3119.AIDB.01.01.0.230101
View, Download and Transmit to a third party	170.315e(1)	NA
Application Access – Patient Selection	170.315(g)(7)	Health Samurai Aidbox 15.99.04.3119.AIDB.01.01.0.230101
Application Access – All Data Request	170.315(g)(9)	Health Samurai Aidbox 15.99.04.3119.AIDB.01.01.0.230101
Standardized API for Patient and Population Services	170.315(g)(10)	Health Samurai Aidbox 15.99.04.3119.AIDB.01.01.0.230101

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
Ambulatory / Outpatient	Willowglade Technologies only provides software that is used in ambulatory settings for oncology practices

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
#1 - 170.315(b)(10) - EHI Export	It is expected that authorized users will be able to share EHI using the export function. This measure is a numeric value of results over a given period of time indicating the number of times the EHI export function has been utilized over a selected period of time. In addition, error rates will be tracked and trended over time using reports and error logs.
#2 - 170.315e(1) - View, Download and Transmit to a third party	It is expected that authorized users will be able to either view, download or transmit EHI using either the view, download or transmit functionality. It is further expected that both human readable and "electronic and computable" formats will be successfully created. Error rates will be tracked and trended over time.

	The measurement will produce numeric results over a selected period of time. Reports and error logs will be used to determine our measure count. Additionally, we will use the measure counts to establish a historic baseline of expected interoperability use so it can be used in subsequent real world testing efforts.
#3 - 170.315g(10) - Standardized API for Patient and Population Services	The measurement will be a numeric result over a given interval. A successful measure indicates use of the underlying ONC criteria. As this feature is not regularly used by our clients, we expect this value to be small. Because of this measure's relationship, this measure should be viewed in conjunction with measure #4.
# 4 - 170.315(g)(7) - Application Access – Patient Selection	The user connects to APIs through a HTTP client that supports HTTPS, and is prompted for credentials and authentication according to our publicly available API documented specification.
170.315(g)(9) - Application Access – All Data Request	After supplying the correct credentials, the portal returns a valid ID or token for the API Client to access the patient data.
170.315g(10) - Standardized API for Patient and Population Services	The user will query the patient clinical data resources via the API and receive access to them through the client application. We will also confirm the process and steps done by the user meets the criteria requirements of the certified module and works as expected in production.
# 5 - 170.204e(1) - Accessibility Testing	An Accessibility testing tool will be used for undertaking this analysis. The metric used will be the count of issues / concerns raised by the use of the accessibility tool that require corrective action to meet the ONC certification criteria. We expect this to be a very small number, or zero.

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
Identify Testing Team Members	Outpatient	Q4 2024
Select time frame for monitoring patient invitations, acceptances etc	Outpatient	Q4 2024
Audit API usage for (g)9 and (g)10)	Outpatient	Q2 2025
Execute on Testing	Outpatient	Q2 2025
Report Test Results (to ONC-ACB)	Outpatient	Q1 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.

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Authorized Representative Signature: Papandrea

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