2025 Real-World Testing Results Report

Darena Health Version 2

Criteria §170.315 (g)(7) & §170.315 (g)(10)

GENERAL INFORMATION

Plan Report ID Number: Real-World Test Results Report_Darena Health_2025

Developer Name: Darena Solutions LLC dba Darena Health

Product Name(s): Darena Health

Version Number(s): Version 2.0

Certified Health IT Product List (CHPL) ID(s): 15.04.04.1322.Blue.02.00.0.200807

Developer Real World Testing Plan Page URL: Darena Health — ONC HTI-1 Certified Solution

Developer Real World Testing Results Report Page URL [if different from above]:

Related ICS Versions of Product (if not included in original plan): N/A

[OPTIONAL] CHANGES TO ORIGINAL PLAN

Summary of Change	Reason	Impact
N/A	N/A	N/A

[IF APPLICABLE] ICS PRODUCT(S)

Product Name(s):	N/A
Version Number(s):	N/A
CHPL ID(s):	N/A
Date(s) of ICS Certification:	N/A

[IF APPLICABLE] WITHDRAWN PRODUCT(S)

Product Name(s):	N/A
Version Number(s):	N/A
CHPL ID(s):	N/A
Date(s) Withdrawn:	N/A

Inclusion of Data in Results Report:	N/A

SUMMARY OF TESTING METHODS AND KEY FINDINGS

The Real-World Testing outcomes confirm that the Darena Health certified module operates as intended within live production environments. Observed results aligned with the interoperability and data-exchange objectives outlined in the approved Real-World Test Plan. Testing emphasized capturing and validating real instances in which the certified capabilities of the Darena Health application were actively used by clients in routine operations.

To substantiate real-world interoperability, observations were directly linked to client deployments supporting certification requirements and compliance with Information Blocking regulations. Darena Health leveraged embedded, automated measurement capabilities to collect usage metrics derived from real patients interacting with the application in production. These metrics provided verifiable evidence of live, end-user utilization rather than simulated or test data.

The Darena Health application retrieves end-user data via FHIR-based API connections, with a focus on patient-requested Electronic Health Information (EHI). EHI includes C-CDA documents populated with USCDI v1 data elements, along with support for additional document formats relevant to patient care and treatment. This architecture enables patients or their authorized representatives to efficiently obtain encounter-level clinical documentation upon request.

Within this workflow, the EHR initiated patient or representative access and supported secure authorization to retrieve information through a third-party application selected by the user, such as Apple Health. Validation steps, consistent with Information Blocking requirements, were observed, including third-party application verification and patient or representative authentication. These end-to-end workflows produced measurable evidence of successful data exchange and interoperability between providers and their real patient populations.

Execution of the Real-World Testing followed a single, continuous test plan and demonstrated consistent results across multiple care settings and clinical specialties. Observations further confirmed that providers and practice staff were able to complete all required tasks independently, without intervention from Darena Health personnel. This unassisted use during live information-sharing activities demonstrates both user adoption and the intended ease of use of the Darena Health application in real-world clinical operations.

STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) STANDARDS UPDATES

Standard (and version)	Updated certification criteria and associated product	Health IT Module CHPL ID	Date of ONC-ACB notification	Date of customer notification	Conformance method and measurement/metric(s)

N/A	N/A	N/A	N/A	N/A	N/A

Care Setting(s)

Real World Testing was performed in ambulatory settings across practices ranging in size up to 150 providers. A diverse mix of clinical specialties was included to ensure that data exchange functionality operates consistently regardless of specialty. Participating practices were drawn from our existing network of providers with live, production-level integrations to the Darena Health platform.

Metrics and Outcomes

This section summarizes the results from Real World Testing conducted using the Darena Health application, as specified in the 2025 MeldRx/Darena Health Real World Testing Plan. Testing captured patient and representative-initiated requests for EHI related to prior encounters, including invitation processing, application validation, authentication, and data delivery. Requests included both partial and complete EHI. Successful completion without vendor support demonstrates ease of use and full interoperability.

Measurement/Metric	Associated Criterion(a)	Relied Upon Software (if applicable)	Outcomes	Challenges Encountered (if applicable)
The patient or authorized representative will be able to access (after authentication) partial summary PHI through an FHIR-based API call from a third-party application running on a patient-owned device through the API of the EHR. Additionally, the success of the MeldRx deployment was demonstrated by the industry leading verified endpoints listed by the Lantern Project, with over 9,000 matching endpoints.	170.315(g)(7): Application Access – Patient Selection 170.315(g)(10): Standardized API for Patient and Population Services	N/A	The Darena Health application operated as expected throughout Real-World Testing, with no defects identified. All testing activities were performed in a secure production environment using live patient data. Results confirmed that clinicians, through their EHR, were able to receive standardized data access requests containing sufficient information to uniquely identify a patient and return an identifier or token enabling subsequent data requests by a third-party application. Testing further demonstrated the EHR's ability to respond to both single-patient and bulk requests for patient data constrained by specific dates or	There were no challenges encountered when testing and collecting data for these criteria.

			defined date ranges. Responses included partial data sets aligned to USCDI v1 data classes, as well as complete electronic health information where requested. Data was returned in accordance with applicable standards and made available to patients or their authorized representatives for viewing and transmission through their selected application and device. Across all test scenarios, the application successfully processed requests for patient data associated with individual dates and defined date ranges. No transaction failures or processing errors were observed, resulting in a measured error rate of zero percent.	

KEY MILESTONES

Key Milestone	Care Setting	Date/Timeframe
Prepare the MeldRx application to collect data upon request by patients/authorized representatives	Ambulatory Setting and Multiple Specialties	December 2024
Identify the user practices that will participate in the test plan	Ambulatory Setting and Multiple Specialties	December 2024 & January 2025
Confirm that the Real-World Test Plan participants can log into their accounts and are ready to demonstrate the request and response for the patient EHI	Ambulatory Setting and Multiple Specialties	January 2025
Follow up with the Real-World Test Plan participants regularly (minimum, once a quarter) to obtain feedback on their progress and address any issues	Ambulatory Setting and Multiple Specialties	Quarterly 2025
End the Real-World Test to coincide with the end of the 2025 Calendar Year	Ambulatory Setting and Multiple Specialties	December 2025
Real World Test analysis and report generation	Ambulatory Setting and Multiple Specialties	January 2026
Submit Real World Test Report to ACB before the established deadline	Ambulatory Setting and Multiple Specialties	February 2026

Attestation

This Real-World Testing plan includes all required elements, including measures that address all certification criteria and care settings. All the information in this plan is current and comprehensively addresses the health IT developer's Real World Testing requirements.

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Date: 2/5/2026