Darena Solutions

MeldRx

2024 Real-World Testing Results Report

MeldRx Version 2

for Criteria

§170.315 (g)(7), §170.315 (g)(10), and §170.315 (b)(10)

GENERAL INFORMATION

Plan Report ID Number: Real-World Test Results Report_MeldRx_2024

Developer Name: Darena Solutions LLC

Product Name(s): MeldRx

Version Number(s): 2

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

Developer Real World Testing Plan Page URL: https://www.darenasolutions.com/meldrx-onc-hti1-certified

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

[OPTIONAL] CHANGES TO ORIGINAL PLAN

If a developer has made any changes to their approach for Real World Testing that differs from what wasoutlined in their plan, note these changes here.

Summary of Change [Summarize each element that changed between the plan and the actual execution of Real World Testing]	**Reason** [Describe the reason this change occurred]	**Impact** [Describe what impact this changehad on the execution of your Real World Testing activities]
N/A	N/A	N/A

[OPTIONAL] WITHDRAWN PRODUCTS

If a developer withdrew any products within the past year that were previously included in their Real-World Testing plan, please provide the following information.

Product Name(s):	N/A
Version Number(s):	N/A
CHPL Product Number(s):	N/A
Date(s) Withdrawn:	N/A
Inclusion of Data in ResultsReport: [Provide a statement as to whether anydata was captured on the withdrawn products. If so, this data should be identified in the results report.]	N/A

SUMMARY OF TESTING METHODS AND KEY FINDINGS

The results of the Real-World Testing verified that the MeldRx certified module does perform as designed in the production environment. The observations documented the interoperability and data exchange as defined in the original test plan. We focused on documenting the number of instances in which the certified criteria of the MeldRx application were successfully used in the real world. To demonstrate the real-world interoperability, we tied our observations to actual efforts that were completed as a part of our clients deploying the application to satisfy the Certify and Provide Information Blocking compliance. We capitalized on the built-in automated testing metrics that collect end-user data from real patients in the live production environment. The MeldRx application acquires end-user data through an FHIR-based API interface and focuses on the patient's desired EHI. EHI is the combination of C-CDAs with the USCDv1 data elements, as well as the ability to incorporate any additional document format that contains information used for the care and or treatment of a patient. This process is used to provide easy access to a patient or their authorized representative with the ability for them to get the encounter documentation upon request. The EHR facilitated the invite for the patient/representative to have secure access to obtain the relevant information through a 3rd-party application of their choice (e.g., Apple Health). The validation was also performed, which is consistent with the Information Blocking requirements to validate the third-party app and authenticate the patient/representative. This workflow provided results for collecting data and successful interoperability workflows between providers and their real patients. We followed our test plan and demonstrated successful real-world implementations with a single and continuous Real World Test Plan and were able to gain confidence that it works in multiple care settings and specialties. We observed that the providers/providers' staff were able to perform the tasks without assistance from Darena staff, as intended by design. Observing the practices of unassisted use of the MeldRx application as a part of the actual Information Sharing demonstrated user acceptance and ease of use.

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.

Indicate whether optional standards, via SVAP and/or USCDI, are leveraged as part of thecertification of your health IT product(s).

☐ Yes, I have products certified with voluntary SVAP or USCDI standards. (If yes,please complete the table below.

☒ No, none of my products include these voluntary standards.

Standard (and version)	N/A
Updated certification criteriaand associated product	N/A
CHPL Product Number	N/A
Conformance measure	N/A

Care Setting(s)

The expectation is that a developer's Real World Testing is conducted within each type of clinical settingin 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.

List each care setting that was tested.

This plan was tested in ambulatory settings with practices of up to 150 providers. It also included testing within practices of different specialties to confirm that the type of specialty does not play a role in the data requests and responses. The participants were recruited from our extensive base of providers/practices that are signed up to have a production interface in place with our MeldRx application.

Metrics and Outcomes

This section details a summary of the results collected from the MeldRx application Real World Testing measures as defined in the MeldRx 2024 Real World Test plan. The outcomes are captured when the users with a MeldRx interface have a request from a patient or designated representative for their EHI from a past encounter with a provider at a given practice. The task was completed after an invite was processed, the third-party app was validated, the patient/representative was authenticated, and their requested data were received on the app. The data requested

can range from partial to full EHI. Completing these tasks without assistance from Darena demonstrated ease of use and full interoperability.

Associated Criterion(a)	Measurement/Metric	Relied Upon Software (if applicable)	Outcomes	Challenges Encountered (if applicable)
170.315(g)(7): Application Access – Patient Selection **170.315(g)(10):** Standardized API for Patient and Population Services (cures Update)	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.	N/A	The MeldRx application performed with zero defects. All activities were conducted within a secure production environment and accessed their real patient data. The Real-World Testing demonstrated that the clinician has the functionality within their EHR to receive a request with sufficient information to uniquely identify a patient and return an ID or other token that can be used by an application to subsequently execute requests for that patient's data. The EHR demonstrated the functionality to respond to specific date range requests for patient data (single and bulk) containing partial data categories	There were no challenges encountered when testing and collecting data for these criteria.

			specified in the USCDI v1 Data Set and including full EHI This one-time return of such data (according to the specified standards, where applicable) allowed the patient /authorized representative to view and transmit the data, as needed, on their application on their selected device. The application responded to requests for patient data associated with a specific date, as well as requests for patient data within a specified date range. A 0% error rate was observed.	
170.315(b)(10): Electronic Health Information Export	Export USCDIv1 clinical data for a population of patients for use in a different health information technology product or a third-party system. This export can be used for many purposes, including data portability when a physician's practice switches to a new EHR platform.	N/A	The MeldRx application performed with zero defects. All activities were conducted within a secure production environment, and the clinician accessed real patient data. The Real-World Testing demonstrated that the clinician has the functionality within their EHR to receive a request with sufficient information to uniquely	The challenge for this (b)(10) criteria was to find a situation where a provider needed to export their data to another EHR. The process was simulated to demonstrated that functionality was achieved.

			identify a patient and return an ID or other token that can be used by an application to subsequently execute requests for that patient's data. The EHR demonstrated the functionality to respond to specific date range requests for patient data (single and bulk) containing partial data categories specified in the USCDI v1 Data Set and including full EHI This one-time return of such data (according to the specified standards, where applicable) allowed the patient/authorized representative to view and transmit the data, as needed, on their application on their selected device. The application responded to requests for patient data associated with a specific date, as well as requests for patient data within a specified date range. A 0% error rate was observed.	

			• Date and time ranges were configured via the UI • Targeted Practices were configured via the UI • Patients exports were configured via the UI • Logging in as a Vendor Admin allowed access to the export functionality. • Logging in as a non-Vendor Admin did not allow access to the export functionality. • Used the Edge Test Tool to check validity of output file C-CDA. • Data was available for the entered date and time range • The export summary contained data only within that date and time range. • Export summary was created and completed successfully • Saving to a preferred location is allowed. • Visually confirming the export after save is performed and successful. • Prepared RWT results	

			report with 95% plus success rate.	

KEY MILESTONES

Include a list of key milestones that were met during the Real World Testing process. Include details on how and when the developer implemented measures and collected data. Key milestones should be relevant and directly related to outcomes discussed.

For each key milestone, describe when Real World Testing began in specific care settings and the date/timeframe during which data was collected.

Key Milestone	Care Setting	Date/Timeframe
Prepared MeldRx for use in the collection of EHI data upon requests by patients/authorized representatives.	Ambulatory Setting	December 2023
Identified the user practices that participated in the test plan.	Ambulatory Setting Multiple Specialties	December 2023 & January 2024
Confirmed that the Real-World Test Plan participants were able to log into their accounts and were ready to demonstrate the request and response for patient EHI.	Ambulatory Setting Multiple Specialties	January 2024
Followed up with the Real-World Test Plan participants on a regular basis (minimum, once a quarter) to obtain feedback on their progress and or if there were any issues to address. Monitor the Lantern Tool for matching endpoints.	Ambulatory Setting Multiple Specialties	Quarterly 2024
Ended the Real-World Test to coincide with the end of the 2024 calendar year.	Ambulatory Setting Multiple Specialties	December 2024
Real World-Test analysis and generation of the report	Ambulatory Setting Multiple	January 2025

	Specialties	
Submit Real-World Test Report to ACB before the established deadline	Ambulatory Setting Multiple Specialties	January 2025

ATTESTATION

The following is an attestation of the Darena Solutions LLC 2024 Real-World Testing Results Report for MeldRx.

This Real World Testing Results Report 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: Wayne Singer

Authorized Representative Email: wayne@darenasolutions.com

Authorized Representative Phone: 832-736-2552

Authorized Representative Signature: 

Date: 1/30/2025