REAL WORLD TESTING PLAN

GENERAL INFORMATION

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

Developer Name: Orchard Software Inc.

Product Name(s): Harvest

Version Number(s): Harvest v12 and v13

Certified Health IT Product List (CHPL) ID(s): 15.07.07.2825.OR02.01.00.0.220531, 15.07.07.2825.OR02.02.01.0.220624

Developer Real World Testing Plan Page URL: https://www.orchardsoft.com/resources/onc-health-it-certifications/

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

Orchard Software's Harvest ELR interface has been designed, tested, and demonstrated to be capable of transmitting messages in accordance with the standards referenced in the criterion, 170.315(f)(3).

During each interface implementation at a client site, the ELR interface is validated with the client and with the state PUBLIC HEALTH AGENCY to meet the needs of the state for interoperability and function. Typically, each reportable test is validated between the client and the state before the interface is used for live data transmission. The interface as implemented at each client is verified to be conformant at the time of installation and is expected to remain so throughout its use.

The goal of this Real World Test is to measure observations of interoperability and data exchange. Orchard Software will employ a non-intrusive method of querying client systems for information about the history of reporting by the ELR interface. Such queries will provide meaningful, quantitative statistical data regarding use of the ELR interface in the field in the form of number of tests qualified for reporting vs. number of tests reported to an individual State PUBLIC HEALTH AGENCY.

Privacy and Security aspects of the measure are established by the mode of transport (VPN, sftp, etc.) chosen by the receiving state PUBLIC HEALTH AGENCY, and are therefore not subject

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to change without the express involvement of the receiving state PUBLIC HEALTH AGENCY.

STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) AND UNITED STATES CORE DATA FOR INTEROPERABILITY (USCDI))

Standard (and version)	No standards updates have been made that affect measure *170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results.*
Updated certification criteria and associated product	Not Applicable
Health IT Module CHPL ID	15.07.07.2825.OR02.01.00.0.220531 15.07.07.2825.OR02.02.01.0.220624
Method used for standard update	Not Applicable
Date of ONC ACB notification	Not Applicable
Date of customer notification (SVAP only)	Not Applicable
Conformance measure	Not Applicable
USCDI updated certification criteria (and USCDI version)	Not Applicable

MEASURES USED IN OVERALL APPROACH

Description of Measurement/Metric

Measurement/Metric	Description
Count of reportable results that qualify and are sent via the ELR Interface	The following counts will be gathered during 3rd quarter 2023 to identify the number of results sent via the ELR interface. Count of the number of qualifying reportable results Count of the Number of reportable results sent via the ELR interface. The numbers should match

Associated Certification Criteria

Measurement/Metric	Associated Certification Criteria	Relied Upon Software (if applicable)
Count of reportable results sent via the ELR Interface	170.315(f)(3)	Not Applicable

Justification for Selected Measurement/Metric

Measurement/Metric	Justification
Count of results that qualify for ELR interface.	The Orchard Software ELR interface is designed to send results that qualify to be reportable to the specified Public Health Agency. This testing will show counts that identify the number of reportable test results processed and qualified to be sent to the Public Health Agency.
Count of results that were sent via ELR interface.	This testing will show counts that identify the number of reportable test results processed, qualified and sent to the Public Health agency. These numbers should match the count of qualified test results to be sent to the Public Health Agency.

Care Setting(s)

Care Setting	Justification
All settings	Orchard Software does not market or install ELR capability differently per care setting. The system is expected to function equally in all care settings and facilities of all sizes.

Expected Outcomes

Measurement/Metric	Expected Outcomes
Count of results that qualify for ELR interface.	Real World testing will identify and count the results that qualify to be transmitted to the Public Health Agency.
Count of results that were sent via ELR interface.	Real World testing will identify and count the results that were transmitted to the Public Health Agency.

SCHEDULE OF KEY MILESTONES

Key Milestone	Care Setting	Date/Timeframe
Submit first draft of CY22 Real World Testing Plan to ACB for review.	All settings	October 17, 2022
Publication of Real World Testing plan.	All settings	December 15, 2022
Identification of clients to be utilized for Real World Testing.	All settings	2nd quarter 2023
Begin collection of information as laid out by the plan.	All settings	July 1, 2023
End of Real World Testing period	All settings	September 30, 2023
Final collection and analysis of all data to be submitted to ACB.	All settings	October 16, 2023
Submit Real World Testing report to ACB (per their instructions).	All settings	January 17, 2024

ATTESTATION

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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