



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 and Orchard Enterprise Laboratory (OEL)

Version Number(s): Harvest v14 and OEL v11

Certified Health IT Product List (CHPL) ID(s): 15.07.09.2825.OR02.14.02.0.230518
15.11.09.2825.ENLB.11.00.0.240618

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 ELR interfaces have been designed, tested, and demonstrated to be capable of transmitting messages in accordance with the standards referenced in the criterion, *170.315(f)(3)* and *170.315(b)(10)*.

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 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 <i>170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results.</i> |
| Updated certification criteria and associated product | Not Applicable |
| Health IT Module CHPL ID | 15.07.09.2825.OR02.14.02.0.230518 15.11.09.2825.ENLB.11.00.0.240618 |
| 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

170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results

Description of Measurement/Metric

| Measurement/Metric | Description |
|---|---|
| Count of reportable results that qualify and are sent via the ELR Interface | <p>The following counts will be gathered during 3rd quarter 2025 to identify the number of results sent via the ELR interface.</p> <p>Count of the number of qualifying reportable results</p> <p>Count of the Number of reportable results sent via the ELR interface.</p> <p>The numbers should match</p> |

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. | Orchard Software ELR interfaces are 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. |

170.315(b)(10) Electronic Health Information export

Use Case 1 – Measure 2

Description of Measurement/Metric

| Measurement/Metric | Description/Requirement |
|---|---|
| EHI export – Single patient population EHI export | <p>This measure will assess functionality used to export EHI for a single patient.</p> <p>Requirement</p> <ul style="list-style-type: none"> (i)(A) Create an export file (i)(B) Execute at any time (i)(C) Limit ability of users who can create export (i)(D) Electronic and computable format |

Associated Certification Criteria

| Measurement/Metric | Associated Certification Criteria | Relied Upon Software (if applicable) |
|--------------------|-----------------------------------|--------------------------------------|
| EHI Export | 170.315(b)(10) | Not Applicable |

| Justification |
|---|
| The export of EHI associated with a patient is another way to share information with an external organization. Export is typically used when there is a need for a full patient record. This metric will provide information on the data exported for a single patient. |

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

| Test Methodology |
|---|
| Security settings will be reviewed to ensure limited ability of users who can create export. The exported data file will be reviewed to validate the proper operation of the export. This test methodology will primarily test the conformance of the implementation. |

| Expected Outcome |
|--|
| It is expected that authorized users will be able to share EHI using the export function. It is also expected that the export will meet published documentation. |

Use Case 2 – Measure 1

Description of Measurement/Metric

| Measurement/Metric | Description/Requirement |
|--|--|
| EHI export – Patient population EHI export | This measure will assess the functionality used to export EHI for a patient population. Requirement (ii)(A) Create an export file |

Associated Certification Criteria

| Measurement/Metric | Associated Certification Criteria | Relied Upon Software (if applicable) |
|--------------------|-----------------------------------|--------------------------------------|
| EHI Export | 170.315(b)(10) | Not Applicable |

| Justification |
|--|
| The export of the health information associated with a patient population is another way to share health information with an external organization. It is typically used for research or quality purposes to look for specific trends on patient population. Export of a patient population is an administrative function only available to credentialed users. It is assumed that this function will be run as a scheduled activity as it will have significant impact on the Health IT Module. |

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

| Test Methodology |
|---|
| Security settings will be reviewed to ensure limited ability of users who can create export. The exported data file will be reviewed to validate the proper operation of the export. This test methodology will primarily test the conformance of the implementation. |

| Expected Outcome |
|--|
| It is expected that authorized users will be able to share EHI using the export function. It is also expected that the export will meet published documentation. |

SCHEDULE OF KEY MILESTONES

| Key Milestone | Care Setting | Date/Timeframe |
|---|--------------|------------------------------|
| Submit first draft of CY25 Real World Testing Plan to ACB for review. | All settings | October 11, 2024 |
| Publication of Real World Testing plan. | All settings | December 15, 2024 |
| Identification of clients to be utilized for Real World Testing. | All settings | 2 nd quarter 2025 |
| Begin collection of information as laid out by the plan. | All settings | July 1, 2025 |
| End of Real World Testing period | All settings | September 30, 2025 |
| Final collection and analysis of all data to be submitted to ACB. | All settings | October 17, 2025 |
| Submit Real World Testing report to ACB (per their instructions). | All settings | January 17, 2026 |

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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Date: 10-14-2024