# REAL WORLD TESTING PLAN TEMPLATE

## 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.

Health IT developers have maximum flexibility to develop innovative plans and measures for Real World Testing. As developers are planning how they will execute Real World Testing, they should consider the overall complexity of the workflows and use cases within the care settings in which they market their certified health IT to determine the approaches they will take. This Real World Testing plan template was created to assist health IT developers in organizing the required information that must be submitted for each element in their Real World Testing plan. While the use of this template is voluntary, health IT developers may find it useful in preparing their Real World Testing plans. Health IT developers must submit one plan for each year of Real World Testing (see resources listed below for specific timelines and due dates). ONC does not encourage updating plans outside the submission timeline and will not post updates on the Certified Health IT Product List (CHPL). If adjustments to approaches are made throughout Real World Testing, the health IT developer should reflect these adjustments in their Real World Testing results report. ONC expects that the Real World Testing results report will include a description of these types of changes, the reasons for them, and how intended outcomes were more efficiently met as a result. **While every effort has been made to ensure the accuracy of restatements of 45 CFR Part 170, this template is not a legal document. The official program requirements are contained in the relevant laws and regulations. This resource should be read and understood in conjunction with the following companion resources, which describe in detail many of the Program requirements referenced in this resource.**

- Real World Testing–What It Means for Health IT Developers – Fact Sheet
- Real World Testing Resource Guide
- Real World Testing Certification Companion Guide

Health IT developers should also review the following regulatory materials, which establish the core requirements and responsibilities for Real World Testing under the Certification Program.

- 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program final rule, 85 FR 25642 (May 1, 2020) (**ONC Cures Act Final Rule**)
    - *Section VII.B.5* — *"Real World Testing"*

## TEMPLATE INSTRUCTIONS

The following template is organized by elements required to be submitted in the Real World Testing plan. Each section provides a field for submitting responses and/or explanations for how the health IT developer

will address each required element in their Real World Testing approach. These fields serve as a foundation of information required for developing a Real World Testing plan and can be expanded with additional rows or columns to address the specific needs of the Real World Testing plan being submitted.

## GENERAL INFORMATION

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

Developer Name: Binh Pham, Si Pham, Anthony Nguyen, Tom Bui

Product Name(s): Universal EHR

Version Number(s): 3.0.0

Certified Health IT Product List (CHPL) Product Number(s): 15.04.04.2478.Univ.02.00.1.19-312/

Developer Real World Testing Plan Page URL: https://www.universalehr.com/rwt/default.aspx

## JUSTIFICATION FOR REAL WORLD TESTING APPROACH

*Provide an explanation for the overall approach to Real World Testing, including an outline of the approach and how data will be used to demonstrate successful Real World Testing.*[i]

*All measures should reasonably align with the elements within a Real World Testing plan, the scope of the certification, the types of settings in which the certified health IT is marketed, and other factors relevant to the implementation of the certified Health IT Module(s). The justification should reflect how each element within the plan is relevant to the developer's overall strategy for meeting the Real World Testing Condition and Maintenance of Certification requirements.*

*Note: A single Real World Testing plan may address multiple products and certification criteria for multiple care settings.*

**We will utilize functional testing to demonstrate Real World Testing in an outpatient clinic care setting. By using an actual outpatient clinic to demonstrate and test each measurement/module, we will be able to collect data to demonstrate the overall accuracy and functionality of the system.**

## 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.*

*Describe approach(es) for demonstrating conformance to all certification requirements using each standard to which the health IT is certified. List each version of a given standard separately. For each version of a standard submit the following:*

- ✓ Identify standard versions
- ✓ Indicate what certification criteria in which product(s) has been updated
- ✓ If reporting for multiple products, identify the certification criteria that were affected by the update for each of the associated products
- ✓ CHPL Product Number for each Health IT Module
- ✓ Method used for standard update (e.g., SVAP)
- ✓ Date notification sent to ONC-ACB
- ✓ If SVAP, date notification sent to customers
- ✓ Measure used to demonstrate conformance with updated standard(s)
- ✓ Which certification criteria were updated to USCDI and/or to which version of USCDI was the certification criteria updated?
- ✓

**For CY 2023, we are not planning to make any version updates on approved standards through the SVAP process.**

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| **Standard (and version)** | None |
| **Updated certification criteria and associated product** | N/A |
| **CHPL Product Number** | N/A |
| **Method used for standard update** | N/A |
| **Date of ONC ACB notification** | N/A |
| **Date of customer notification (SVAP only)** | N/A |
| **Conformance measure** | N/A |
| **USCDI updated certification criteria (and USCDI version)** | N/A |

## MEASURES USED IN OVERALL APPROACH

*Each plan must include at least one measurement/metric that addresses each applicable certification criterion in the Health IT Module's scope of certification. Describe the method for measuring how the approach(es) chosen meet the intent and purpose of Real World Testing.*

For each measurement/metric, describe the elements below:

- ✓ Description of the measurement/metric
- ✓ Associated certification criteria
- ✓ Justification for selected measurement/metric
- ✓ Care setting(s) that is addressed

- ✓ Expected outcomes

### Description of Measurement/Metric

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

| Measurement/Metric | Description |
|---|---|
| **Measure 1**: Send Patient Health Information via Direct Messaging | Universal EHR uses EMR Direct as its direct messaging vendor to send and receive direct messages containing patient health information from other providers for transition and continuity of care events. This measure tracks how many CCDAs are generated and successfully sent from the EHR to a 3rd party using direct messaging over a given time period. Any errors will be recorded and analyzed. |
| **Measure 2**: Incorporating Patient Health Information via Direct Messaging | This measure tracks how many CCDAs are successfully received from a 3rd party via direct messaging and incorporated into Universal EHR. Patient data received including medication list, problem list and allergy list will be incorporated and updated into the patient's chart accordingly. Any errors will be recorded and analyzed. |
| **Measure 3**: Number of Electronic Prescriptions Successfully Sent | Universal EHR uses NewCropRx as its electronic prescribing vendor for providers to send prescriptions electronically. This measure tracks the rate of successful prescription transmissions from the EHR to pharmacies over a given time period. Any errors will be recorded and analyzed. |
| **Measure 4**: Export Patient Data | Authorized users will be able to download and export patient data/clinical summaries through CCDA format. This measure tracks the rate of successful exports. Any errors will be recorded and analyzed. |
| **Measure 5**: Report of Clinical Quality Measures | Users will be able to generate a report of Clinical Quality Measures from the Universal EHR that will be reported to CMS during the MIPS reporting period. This measure tracks the rate of successful generation of these reports. Any errors will be recorded and analyzed. |
| **Measure 6**: Patient Portal Use | Patients will be given access to the Universal EHR patient portal to view their health information. This measure will track how many patients have logged into the portal over a given time period. |
| **Measure 7**: Transmission to Immunization Registries | Patient immunization records are recorded in the EHR and an HL7 immunization message will be generated and sent directly to CAIR (California Immunization Registry). This measure will track the rate of successful transmission of immunization messages from the EHR to the immunization registry over a given time period. Any errors will be recorded and analyzed. |
| **Measure 8**: Transmission to Public Health Agencies – Syndromic Surveillance | Users will export syndromic surveillance information from the EHR and export them to the state's registry via HL7 files. This measure will track the rate of successful file creations and transmission. Any errors will be recorded and analyzed. |

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| **Measure 9**: Compliance of API Resource Query Support | This measure is tracking compliance of the EHR Module criteria functionality of support of API query of patient data resources. |

### Associated Certification Criteria

*List certification criteria associated with the measure and if updated to the 2015 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.*

| Measurement/Metric | Associated Certification Criteria | Relied Upon Software (if applicable) |
|---|---|---|
| **Measure 1**: Send Patient Health Information via Direct Messaging | 170.315 (b)(1): Transitions of Care | phiMail Server |
| **Measure 2**: Incorporating Patient Health Information via Direct Messaging | 170.315 (b)(2): Clinical Information Reconciliation and Incorporation | |
| **Measure 3**: Number of Electronic Prescriptions Successfully Sent | 170.315 (b)(3): Electronic Prescribing | NewCropRX |
| **Measure 4**: Export Patient Data | 170.315 (b)(6): Data Export | |
| **Measure 5**: Report of Clinical Quality Measures | 170.315 (c)(1): Clinical Quality Measures - Record and Export<br>170.315 (c)(2): Clinical Quality Measures - Import and Calculate<br>170.315 (c)(3): Clinical Quality Measures - Report | |
| **Measure 6**: Patient Portal Use | 170.315(e)(1) View, download, and transmit to 3rd party | |
| **Measure 7**: Transmission to Immunization Registries | 170.315 (f)(1): Transmission to Immunization Registries | |
| **Measure 8**: Transmission to Public Health Agencies – Syndromic Surveillance | 170.315 (f)(2): Transmission to Public Health Agencies – Syndromic Surveillance | |

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| **Measure 9**: Compliance of API Resource Query Support | 170.315(g)(7) Application access - patient selection<br>170.315(g)(8) Application access - data category request<br>170.315(g)(9) Application access - all data request | |
| **Measure 10**: Direct Project | 170.315(h)(1) Electronic Exchange – Direct Project | PhiMail Server |

### Justification for Selected Measurement/Metric

*Provide an explanation for the measurement/metric selected to conduct Real World Testing.*

| Measurement/Metric | Justification |
|---|---|
| **Measure 1**: Send Patient Health Information via Direct Messaging | The export of electronic health information to other organizations is important when patients are referred to other providers and patient information is required to be shared with those providers. |
| **Measure 2**: Incorporating Patient Health Information via Direct Messaging | This measure allows authorized users to view transition of care summaries, and download and transmit them to other organizations, serving as another method of sharing EHI to other providers. |
| **Measure 3**: Number of Electronic Prescriptions Successfully Sent | Prescribing medications is an important aspect of health care and is a common form of treatment. The ability to send prescriptions electronically to patient's preferred pharmacy makes it more efficient for all parties involved. This measure will provide a numeric value on the success rate of prescription transmission from the EHR to pharmacies. |
| **Measure 4**: Export Patient Data | Batch data export enables authorized users to download data for multiple patients via CCDA and sending it to another care setting. This measure will provide a numeric value on the success rate of exporting patient data. |
| **Measure 5**: Report of Clinical Quality Measures | Providers enrolled in CMS (Medicare) are required to submit clinical quality measures for MIPS reporting annually. Users will generate a report from the EHR database that will satisfy the quality measure requirements to submit to CMS. This measure will provide a numeric value on the success rate of generating these reports. |
| **Measure 6**: Patient Portal Use | The use of patient portals enhances patient engagement by enabling patients to access their electronic medical records and facilitating secure patient-provider communication. This measure will provide a |

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| | numeric value on how many patients logged into the portal and compare it to the number of patients seen over the same given time period. |
| **Measure 7**: Transmission to Immunization Registries | Some providers are required to report immunizations to their state immunization registry. This measure will provide a numeric value on the success rate of transmitting immunization messages via HL7 files from the EHR to the immunization registry. |
| **Measure 8**: Transmission to Public Health Agencies – Syndromic Surveillance | While Universal EHR has the capability to transmit HL7 messages and report to outside registries, to date we have not been asked to set up a real world connection to any such agency. In the meantime, we will conduct internal testing to ensure compliance. |
| **Measure 9**: Compliance of API Resource Query Support | Because our API is not actively being used by clients, we will conduct real world testing using test patients to ensure compliance. |
| **Measure 10**: Direct Project | 170.315(h)(1) Electronic Exchange – Direct Project |

### 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 |
|---|---|
| Outpatient Clinic | UniversalEHR currently markets to outpatient clinic settings only, and therefore will focus on an outpatient primary care clinic setting concerning Real World Testing. |

### 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 |
|---|---|
| **Measure 1**: Send Patient Health Information via Direct Messaging | This measure will track the number of CCDA files sent electronically to 3rd parties via direct messaging. There will be a numeric result and the number of CCDAs will be reported over a 3-month period. |
| **Measure 2**: Incorporating Patient Health Information via Direct Messaging | This measure will track the success rate of receiving patient health information from a 3rd party in CCDA format and incorporating the information into the patient's chart. Once the CCDA has been received and downloaded, it is expected that the user will reconcile the CCDA and update, at minimum, the medication and allergy lists in the patient's chart. This will produce numeric results and be reported over a 3-month period. |
| **Measure 3**: Number of Electronic Prescriptions Successfully Sent | It is expected that all prescribed medication should be created and transmitted to the pharmacy through NewCropRx with no errors. This measurement will track the success rate of the prescription transmission and produce numeric results over a given time period. |
| **Measure 4**: Export Patient Data | It is expected that authorized users will be able to successfully download and export patient data for multiple patients at a time. This measurement will produce a numeric result on the success rate of exporting patient data. |
| **Measure 5**: Report of Clinical Quality Measures | It is expected that the Clinical Quality Measures (CQM) report will be generated and exported successfully without any errors. This measurement will track the success rate of generating and exporting such reports and produce numeric results over a given time period. |
| **Measure 6**: Patient Portal Use | It is expected that patients will be able to successfully log in to their patient portal to securely view, download or transmit their health |

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| | information. This measurement will track the number of patients who logged in to the portal and compare it to the number of patients seen during given time period. This will produce numeric results. |
| **Measure 7**: Transmission to Immunization Registries | It is expected that HL7 immunization messages will export successfully and be transmitted to CAIR (CA Immunization Registry) with no errors. The transmitted information is expected to match the information on the patient's chart and the information that will be displayed by CAIR. This measurement will track the success rate of the immunization message transmission and produce numeric results over a 3-month period. |
| **Measure 8**: Transmission to Public Health Agencies – Syndromic Surveillance | We will conduct internal testing to ensure compliance by testing the capability to send HL7 messages containing syndromic data. It is expected that the HL7 messages will be exported and transmitted successfully without errors. This measurement will track the success rate of the message transmission and produce numeric results over a 3-month period. |
| **Measure 9**: Compliance of API Resource Query Support | The 3rd party user will be given access to the EHR through a client application via the API. The user must enter in the correct credentials in order to access the patient data. We expect that the API will return the appropriate data for the specific patient requested. |
| **Measure 10**: Direct Project | 170.315(h)(1) Electronic Exchange – Direct Project |

## 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 |
|---|---|---|
| Release of documentation of Real World Testing to be provided to authorized representatives and providers testing the measurements/metrics. | Outpatient Clinic | 12/1/2022 |
| Begin data collection. | Outpatient Clinic | 1/1/2023 |
| Meet with providers and authorized representatives to ensure Real World Testing protocols are effective. | Outpatient Clinic | 2/1/2023 |

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| Follow up with providers and authorized representatives regarding data collection. | Outpatient Clinic | Quarterly, 2023 |
| Data collection and review. | Outpatient Clinic | Quarterly, 2023 |
| End of Real World Testing period, finalize collection of all data for analysis. | Outpatient Clinic | 1/1/2024 |
| Analysis and report creation | Outpatient Clinic | 1/15/2024 |
| Submit Real World Testing report | Outpatient Clinic | 2/1/2024 |

## 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.*[ii]

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.

Authorized Representative Name: Binh Pham

Authorized Representative Email: binhpham@universalehr.com

Authorized Representative Phone: (714) 799 - 5005

Authorized Representative Signature: Binh Pham

Date: 12/14/2022

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[i] Certified health IT continues to be compliant with the certification criteria, including the required technical standards and vocabulary codes sets; certified health IT is exchanging EHI in the care and practice settings for which it is marketed for use; and EHI is received by and used in the certified health IT. (85 FR 25766) [ii] https://www.federalregister.gov/d/2020-07419/p-3582