# REAL WORLD TESTING PLAN

## BACKGROUND & INSTRUCTIONS

Under the ONC Health IT Certification Program (**Program**), Health IT Developers are required to conduct Real World Testing of their Certified Health IT (45 CFR 170.556 and 170.523(i)). 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 to develop 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 for 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 which 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. 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 would expect 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. 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 – Coming Soon
- 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 Program.

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

## GENERAL INFORMATION

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

Developer Name: CPSI (Computer Programs and Systems), Inc.

Product Name(s): Centriq Clinic EHR

Version Number(s): 14, 15

Certified Health IT

Product List (CHPL) ID(s): 15.04.04.2751.Cent.EP.01.1.171226, 15.04.04.3104.Cent.EP.02.1.220817

Developer Real World Testing Page URL: https://www.cpsi.com/resources/real-world-testing

## JUSTIFICATION FOR REAL WORLD TESTING APPROACH

Consistent with the ONC's recommendation that "Real World Testing verify that deployed Certified Health IT continues to *perform as intended by conducting and measuring observations of interoperability and data exchange*", this test plan focuses on capturing and documenting the number of instances that certified capability is successfully utilized in the real world. In instances where no evidence exists due to zero adoption of a certified capability or the inability to capture evidence of successful use for other reasons, we will demonstrate the required certified capability in a semi-controlled setting as close to a "real world" implementation as possible.

It is important to note that Real World Testing is only one component of the Health IT Certification program used to demonstrate compliance with the program requirements. Real World Testing should augment and support testing that was conducted prior to certification being granted. It is not intended to duplicate the methods or results previously demonstrated. Instead, this test plan was developed to demonstrate that the certified capabilities have been successfully deployed for providers to use at their discretion in live settings.

We are using a 3-fold approach to demonstrate successful real-world implementations.

- Adoption Rate
- Summative Testing
- Interactive Testing via User Stories

Adoption rate will be used to determine if/when certified capability is being used in the real world and to help identify differences in care settings. Evidence of high rates of implementation and usage indicate (but don't by themselves prove) a certified capability's usefulness and practical value. Evidence of low rates of implementation and usage might indicate a potential problem, of which there could be several different causes. Note, it is not the goal of this exercise to identify the individual causes of why a given certified capability may have a high or low adoption rate, but rather to identify the users and care settings for which a given test is relevant.

Summative assessments will be used to measure which certified actions were performed at the conclusion of a given time period. These will be conducted by running reports and examining audit logs from within the certified health IT module to help demonstrate the frequency of actions within the given time frame, and where possible, whether those actions were successful or unsuccessful. High success rates should be an indicator of a successful implementation of a given certified capability in a real-world setting.

Interactive testing will be used to demonstrate conformance to requirements where the adoption rate of a given certified capability is zero and to demonstrate ongoing compliance with updated standards and code sets (SVAP). Interactive tests will require a live test as opposed to examining historical usage statistics. Interactive tests will be demonstrated by defining "user stories". The goal is to allow a user to demonstrate the certified Health IT module being used in a way consistent with their own practice or care setting.

## STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS-SVAP AND USCDI)

Centriq Clinic EHR has been updated to USCDI v1 specifications to conform to Cures Update criteria which utilize USCDI.

## CARE SETTINGS

Centriq Clinic is marketed primarily to primary care physicians in ambulatory settings. Centriq Clinic does not contain any specialty apps.

| Care Setting | Justification |
|---|---|
| Primary Care Provider Clinics | Centriq Clinic is marketed to Ambulatory providers (mostly PCP). The product does not contain any specialty apps. Centriq Clinic is used by Ambulatory PCPs that are associated with hospital systems using the Inpatient Centriq EHR. Centriq Clinic is not sold independently. It resides on the same server as Centriq. |

## MEASURES USED IN OVERALL APPROACH

For each measurement/metric, describe the elements below:

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

## ADOPTION RATES

The following metrics are applicable to all criteria and all care settings. These metrics will not be used directly to demonstrate interoperability or conformance to certification criteria. Instead, they will primarily be used to help determine the participants that will be in scope for this evaluation. They can also aid with the justification for other metrics by providing additional context (i.e., extremely low adoption rates for certain certified capabilities will necessitate a different approach to testing).

| Metric | Description |
|---|---|
| Number of licensed installs/users of EHR<br>• The definition of a "license" is dependent upon the model used (e.g., total number of systems, total number of seats per license, etc.) | Identify the total number of licensed installs/users of the certified Health IT module, regardless of care setting, participation in incentive programs, or use of certified capabilities.<br>91 |

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| Number of active installs/users of EHR | Identify the total number of ***active*** installs and/or users of the certified Health IT module, regardless of care setting, participation in incentive programs, or use of certified capabilities.<br>77 |

The following metrics are applicable to all criteria and all care settings. These metrics will not be used directly to demonstrate interoperability or conformance to certification criteria. Instead, they will primarily be used to help determine the participants that will be in scope for this evaluation. They can also aid with the justification for other metrics by providing additional context (i.e., extremely low adoption rates for certain certified capabilities will necessitate a different approach to testing).

The most common is using the Software as a Service (SaaS) where the software is provided for a monthly fee. Most of our software application licenses are without a limitation on the number of concurrent users that may access the application.

Some applications, including system access software, are on a per concurrent user basis. Applications that are per user are identified in the proposal by the listing of the number of user licenses and also can be provided at the facility's option as a "site" license. When such software is a site license, the facility may provide access to as many concurrent users as desired without incurring any additional fees.

Example applications per user are Electronic Prescribing, and Direct Messaging.

The following metrics are applicable to all criteria that are licensed separately from the base license and all care settings.

| Metric | Description |
|---|---|
| Certified capabilities that are licensed separately | Identify which certified capabilities are licensed separately from the base EHR license. Examples may include eRx, CQMs, public health, etc.<br>Electronic Prescribing, Direct Messaging |
| Number of installs/users who licensed a certified capability | Where applicable, identify the number of licensed installs/users of a given certified capability.<br>Epres cribing 77sites<br>Direct Messaging 185 addresses ( shares with Centriq) |
| Number of installs/users that have used the certified capability in the preceding 365 days | Where applicable, identify the number of ***active*** installs/users of a given certified capability.<br>Epres cribing 77 sites<br>Direct Messaging 185 addresses |

The following metrics will be measured by viewing audit logs and reporting systems available to track the behavior of the certified Health IT module during a given time frame. All metrics are designed to reflect the core elements of the criteria, demonstrate interoperability, and demonstrate the success rate of the certified capability being used. In most cases we elected to record these metrics over a 90-day period to reflect the reporting periods typically required for compliance with the federal incentive programs.

The continued measurable use of certified capabilities will provide implicit evidence of successful implementation of the required certified capability. This is especially meaningful in cases where interoperability with outside systems is demonstrated. In cases where it is not possible to determine "success" via an explicit confirmation by a receiving system, success will be defined as a transmission was made where no error was received from the destination system or its intermediaries. Additionally, we will review internal customer and vendor issue tracking systems for reports of failures or unsatisfactory performance in the field.

ALL of the following criteria were updated to the Cures Update version of criteria August 17, 2022 in the version 15 certification. Version 14 technically remains active and testing is the same for either version. As a result, all testing is scheduled to be conducted against the 2015 Edition Cures Update version of the criteria.

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| Criterion | Metric | Care Setting | Justification and Expected Outcome |
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| 170.315(b)(1) Transitions of care | Over a 90-day period:<br>1) Number of CCDAs created<br>2) Number of CCDAs sent via edge protocols<br>3) Number of CCDAs received via edge protocols | Primary Care Provider Clinics | This criterion requires the ability of a certified Health IT module to create CCDAs according to specified standards and vocabulary code sets, as well as send and receive CCDAs via edge protocols. However, it is not possible to consistently and reliably demonstrate that all required standards and code sets were used because not all CCDAs created in a real-world setting contain all the necessary data elements. Furthermore, it is not feasible to obtain copies of CCDA documents from "outside" developers or providers who have no incentive to participate in this exercise. Therefore, we intend to demonstrate the required certified capabilities by demonstrating how often CCDAs are created and exchanged with other systems via connection to a HISP for a successful transmission. This will demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be moderate utilization by providers with a high success rate.<br>Relied Upon Software: Updox |

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| 170.315(b)(2) Clinical information reconciliation and incorporation | Over a 90-day period:<br>1) Number of times a user reconciled medication list data from a received CCDA<br>2) Number of times a user reconciled allergies and intolerance list data from a received CCDA<br>3) Number of times a user reconciled problem list data from a received CCDA | Primary Care Provider Clinics | This criterion requires the ability of a certified Health IT module to take a CCDA received via an outside system and match it to the correct patient; reconcile the medication, allergy, and problem lists; and then incorporate the lists into the patient record. The expectation is each of these steps is done electronically within the certified Health IT module. While this certified capability is available to our users, most providers in the real world typically prefer to perform these steps manually and elect to save any outside received CCDAs as attachments to the patient record. Therefore, we intend to record the frequency that providers are electronically reconciling and incorporating CCDAs that were received from outside providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be low utilization by providers with a high success rate. |
| 170.315(b)(3) Electronic prescribing | Over a 90-day period:<br>1) Number of prescriptions created<br>2) Number of prescriptions changed<br>3) Number of prescriptions canceled<br>4) Number of prescriptions renewed | Primary Care Provider Clinics | This criterion requires the ability of a certified Health IT module to perform prescription-related electronic transactions (eRx) using required standards. This functionality is provided by Dr First. However, it is not possible to demonstrate the correct standards were used because it is not feasible to obtain copies of eRx documents from "outside" companies or pharmacies who have no incentive to participate. Therefore, we intend to demonstrate the required certified capabilities are effective by demonstrating how often eRx transactions are performed by examining reports from our eRx partner. This will demonstrate that not only are the eRx transactions sent from the certified Health IT module, but that the transactions are successfully received by the eRx clearinghouse. Our expectation is there will be high utilization by providers with a high success rate. |

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| 170.315(b)(6) Data export | Over a 90-day period:<br>1) Number of times a data export was performed, whether for a single patient, multiple patients, or for all patients | Primary Care Provider Clinics | This criterion requires the ability of a certified Health IT module to export a summary of a patient's record in CCDA format according to specified standards and vocabulary code sets. However, it is not possible to consistently and reliably demonstrate that all required standards and code sets were used because not all CCDAs created in a real-world setting contain all the necessary data elements. Therefore, we intend to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be very low utilization by providers with a high success rate. |
| 170.315(f)(1) Transmission to immunization registries | Over 3 separate unique 10-day periods within a 90-day window:<br>1) Number (or percentage) of immunization records submitted to the immunization record | Primary Care Provider Clinics | This criterion requires the ability of a certified Health IT module to transmit immunization data to a registry using a specified format. We intend to record the frequency that immunization data is submitted to registries by providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be low utilization by providers with a high success rate. |
| 170.315(f)(2) Transmission to public health agencies — syndromic surveillance | Over 3 separate unique 10-day periods within a 90-day window:<br>1) Total number of syndromic surveillance events created and submitted | Primary Care Provider Clinics | This criterion requires the ability of a certified Health IT module to transmit syndrome-based public health surveillance data to a registry using a specified format. We intend to record the frequency that syndromic surveillance data is submitted to registries by providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be low utilization by providers with a high success rate. |
| 170.315(f)(4) Transmission to cancer registries | Over 3 separate unique 10-day periods within a 90-day window:<br>1) Total number of cancer registry data records created and submitted | Primary Care Provider Clinics | This criterion requires the ability of a certified Health IT module to transmit cancer case information to a registry using a specified format. We intend to record the frequency that cancer case information is submitted to registries by providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will continue to be zero adoption of this certified capability by our users, so we have added interactive testing methodology for these capabilities to the test plan below to demonstrate the feature is available and functions as expected should any users elect to begin using this feature.<br>Relied Upon Software: N/A |

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| 170.315(f)(5) Transmission to public health agencies — electronic case reporting | Over 3 separate unique 10-day periods within a 90-day window:<br>1) Total number of electronic case reports created and submitted | Primary Care Provider Clinics | This criterion requires the ability of a certified Health IT module to identify which encounters may be reportable and then create an electronic case report for transmission to a registry using a specified format. We intend to record the frequency that electronic case reports are created and submitted by providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used. The IPPS rule incorporated additional functionality for the bi-directional exchange of eCR, effective Dec 31 2022. As all facilities will be mandated to initiate the bidirectional exchange in 2023, we anticipate subsequent adoption of the expanded functionality by our customers in the 2023 reporting year. Until then there is no way to demonstrate it in the live environment, so we have added interactive testing methodology for these capabilities to the test plan below to demonstrate the feature is available and functions as expected should any users elect to begin using this feature. |
| 170.315(f)(7) Transmission to public health agencies — health care surveys | Over 3 separate unique 10-day periods within a 90-day window:<br>1) Total number of health care surveys created and submitted | Primary Care Provider Clinics | This criterion requires the ability of a certified Health IT module to transmit health care survey information to a registry using a specified format. We intend to record the frequency that health care survey information is submitted to registries by providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be zero adoption of this certified capability by our users, so we have added interactive testing methodology for these capabilities to the test plan below to demonstrate the feature is available and functions as expected should any users elect to begin using this feature. |

## INTERACTIVE TESTING

The following test plans will be executed to demonstrate Real World certified capabilities for criteria where metrics are not available, because there is no adoption to date of these criteria in the Real World, either due either due to unanticipated lack of interest or other factors. Where applicable, these factors are described below.

CPSI will leverage interactive testing for the following criteria for Centriq Clinic:

- §170.315(f)(4) Transmission to cancer registries
- §170.315(f)(5) Transmission to public health agencies — electronic case reporting

- §170.315(f)(7) Transmission to public health agencies — health care surveys

***High Level Interactive Test Plan***

- **Public Health Criteria Test Environment:**
  - CPSI Public Health certified capabilities were developed to be purchased as a separate module, which requires extensive configuration to be setup to be used. As such, CPSI will perform Interactive Testing for these criteria using a near-prod environment that is set up as a mirror of Real-World Deployed Environments.

| Criterion | Interactive Test Plan | Justification and Expected Outcome |
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| §170.315(f)(4) Transmission to cancer registries | CPSI will create 3 different Oncology patients and their representative data in the CPSI production system.<br>These test patients will include a test patient with a Cancer diagnosis with no treatment, as well as 2 patients with Cancer diagnoses with different prescribed treatments.<br><br>CPSI will walk through the Centriq Clinic system, mimicking the intended workflow of an Oncology Clinician and use the manual generation feature to generate 3 Cancer CCDA documents, then use visual inspection to confirm that the documents include all the expected content for each patient and uses SNOMED and LOINC value sets per the required standard. | **Justification:**<br>There are no customers currently using this certified capability in the field. CPSI has found that while providers initially signed up to use this feature, when the reporting requirement became optional, all the providers who were signed up decided not to use it.<br><br>Additionally, CPSI does not have any Oncology specialist providers utilizing the Centriq Clinic product at this time.<br><br>**Expected Outcome:**<br>The CCDA documents will be generated for each patient and will include the correct value sets. |

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| §170.315(f)(5) Transmission to public health agencies — electronic case reporting | CPSI developed this workflow as an automatic workflow that runs in the background. Whenever a diagnosis, lab result or medication is entered, it is checked against a trigger table. When a match occurs, it creates a report and sends it to the Interface Management System (IMS). Reports can be viewed in the Interface Management System (IMS) prior to being sent to a Registry.<br><br>CPSI will create 3 test patients, each one with a different encounter or parameter that matches the trigger code table, as well as representative data for that encounter, including:<br>○ Encounter diagnoses and their associated ICD10 code<br>○ Provider's contact information<br>○ Reason for visit<br>○ Patient Name<br>○ Sex<br>○ Date of Birth<br>○ Race and Ethnicity<br>○ Preferred language<br>○ Problems<br>○ Medications<br>○ Laboratory Tests<br>○ Laboratory Values(s)/Result(s)<br>○ Vital Signs<br>○ Procedures<br>○ Care Team Member(s)<br>○ Immunizations<br>○ Assessment and Plan of Treatment<br><br>CPSI will document the patient encounter in the Centriq Clinic and satisfy the trigger conditions, then use visual inspection of the Interface Management System (IMS) to show that the trigger resulted in a transmission of the expected data for each patient to the Interface Management System (IMS). | Justification:<br>There are no sites using Electronic Case Reporting. The reason for this is that when CMS reduced the number of public health reportable that were needed, most providers already had the required number and did not adopt this new functionality. The IPPS rule incorporated additional functionality for the bi-directional exchange of eCR, effective Dec 31 2022. As all facilities will be mandated to initiate the bidirectional exchange in 2023, we anticipate subsequent adoption of the expanded functionality by our customers in the 2023 reporting year. Until then there is no way to demonstrate it in the live environment, so we have added interactive testing methodology for these capabilities to the test plan below to demonstrate the feature is available and functions as expected should any users elect to begin using this feature<br><br>**Expected Outcome:**<br>Interface Management System (IMS) system will show 3 case reports for patient encounters showing the expected CPSI patient data. Visual inspection will confirm that this functionality is available for deployment in a production environment and ready to be configured and deployed to a customer system. |

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| §170.315(f)(7) Transmission to public health agencies — health care surveys | CPSI will create 3 test patients, representing 2 Outpatient settings and 1 Urgent Care provider, and their representative data in the Production system.<br><br>CPSI will create health care survey documents and manually download the Healthcare Survey documents.<br>CPSI will use the NIST healthcare surveys Release 1.2 validator found here: https://cda-validation.nist.gov/cda-validation/muNHCS.html to confirm that the documents confirm to expected standards. | **Justification:**<br>There are no sites using Health Care Survey Reporting. The reason for this is that when CMS and ONC reduced the number of public health reportable that were needed, most providers already had the required number and did not adopt this new functionality.<br><br>**Expected Outcome:**<br>3 Healthcare survey documents are created and pass validation |

## SCHEDULE OF KEY MILESTONES

Real World test planning will commence in first quarter of 2023. Each phase is expected to take 90-days to complete, with report writing to occur end of 2023/early 2024.

| Key Milestone | Care Setting | Date/Timeframe |
|---|---|---|
| Scheduling and logistics | Primary Care Provider Clinics | 90-days |
| Data collection | Primary Care Provider Clinics | 90-days |
| Review and collate data | Primary Care Provider Clinics | 90-days |
| Writing report | Primary Care Provider Clinics | 90-days |

## 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: November 1, 2022