

Test Procedure for §170.314(c) Clinical quality measures

This document describes the test procedure for evaluating conformance of complete EHRs or EHR modules to the certification criteria defined in 45 CFR Part 170 Subpart C of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule. The document¹ is organized by test procedure and derived test requirements with traceability to the normative certification criteria as described in the Overview document located at [available when final]. The test procedures may be updated to reflect on-going feedback received during the certification activities.

The Department of Health and Human Services (HHS)/Office of the National Coordinator for Health Information Technology (ONC) has defined the standards, implementation guides and certification criteria used in this test procedure. Applicability and interpretation of the standards, implementation guides and certification criteria to EHR technology is determined by ONC. Testing of EHR technology in the Permanent Certification Program, henceforth referred to as the ONC Health Information Technology (HIT) Certification Program², is carried out by National Voluntary Laboratory Accreditation Program (NVLAP)-Accredited Testing Laboratories (ATLs) as set forth in the final rule establishing the Permanent Certification Program (*Establishment of the Permanent Certification Program for Health Information Technology, 45 CFR Part 170; February 7, 2011*).

Questions or concerns regarding the ONC HIT Certification Program should be directed to ONC at ONC.Certification@hhs.gov.

CERTIFICATION CRITERION

This test plan documents the procedure for testing electronic health record (EHR) technology for the calculation and reporting of Clinical Quality Measure (CQM) results as set forth in the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology Final Rule (September 4, 2012) issued by the Department of Health and Human Services (HHS). Applicable sections of this rule include:

§170.314(c) Clinical quality measures.

(1) Clinical Quality Measures – capture and export.

(i) Capture. For each and every CQM for which the EHR technology is presented for certification, EHR technology must be able to electronically record all of the data identified in the standard

¹ Disclaimer: Certain commercial products may be identified in this document. Such identification does not imply recommendation or endorsement by ONC.

² Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule.

specified at § 170.204(c) that would be necessary to calculate each CQM. Data required for CQM exclusions or exceptions must be codified entries, which may include specific terms as defined by each CQM, or may include codified expressions of “patient reason,” “system reason,” or “medical reason.”

(ii) Export. EHR technology must be able to electronically export a data file formatted in accordance with the standards specified at § 170.205(h) that includes all of the data captured for each and every CQM to which EHR technology was certified under paragraph (c)(1)(i) of this section.

(2) Clinical Quality Measures – import and calculate.

(i) Import. EHR technology must be able to electronically import a data file formatted in accordance with the standard specified at § 170.205(h) and use such data to perform the capability specified in paragraph (c)(2)(ii) of this section. EHR technology presented for certification to all three of the certification criteria adopted in paragraphs (c)(1) through (3) of this section is not required to meet paragraph (c)(2)(i)

(ii) Calculate. EHR technology must be able to electronically calculate each and every clinical quality measure for which it is presented for certification.

(3) Clinical Quality Measures – electronic submission. Enable a user to electronically create a data file for transmission of clinical quality measurement data:

(i) In accordance with the standards specified at § 170.205(h) and (k); and

(ii) That can be electronically accepted by CMS.

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ADDRESSING CERTIFICATION CRITERIA §170.314(c)

This plan outlines a testing procedure that addresses §170.314(c) by utilizing the CQM testing software Cypress as the principal means for conducting and facilitating the testing of electronic health record software systems' capability to meet the CQM certification criteria. While the Cypress software does provide some automated functions for testing CQMs, it is expected that trained Testers will be administering the tests and performing the manual steps necessary to complete the tests both from within the Cypress software workflow and outside of it.

The test procedure described in this document specifically addresses the certification criteria in the following ways:

- Clinical Quality Measures – Capture and Export
Test data is provided by the Cypress software that references all of the necessary quality data model elements for each of the CQMs for which the EHR technology is being certified. This test procedure calls for the capture of this data in either a manual or automated fashion and for this test data to be exported for upload and inspection from the EHR system during the test. The inspection will happen within the Cypress user interface with automated feedback displayed to aid the Tester in their evaluation. The Cypress software does not explicitly test the capture capability as required of an EHR system under test by the certification criteria, however, this test procedure describes the inspection process that should be taken by the trained Tester to ensure the capability is met using the Cypress provided test data.
- Clinical Quality Measures – Import and Calculate
This test procedure uses test data provided by the Cypress software in various electronic formats (including the standard recognized at §170.205(h)) and calls for the presentation of this data to an EHR for processing and as input into the EHR technology during the test. This procedure then calls for the trained Tester to perform an inspection of the functions described by the EHR vendor for calculating each CQM the EHR system is being tested for and to validate that electronic calculation is performed on the test data provided by the Cypress software.
- Clinical Quality Measures – Electronic Submission
As part of this test procedure, the EHR technology exports the results of the calculation performed during the calculate portion of the test in both of the formats described in the certification criteria (§170.205(h) and (k)). The Tester uploads the QRDA Category III aggregate summary report via the Cypress user interface and receives comparison feedback on both the expected calculation results and the expected structure and format of the document in accordance with the QRDA Category III data standard specification.

The detailed descriptions of the expected Tester workflow and interaction with the EHR system under test can be found in the Informative and Normative test procedure sections of this document.

A number of terms are used in this test plan. This section enumerates those terms and defines how they are used in the context of this document.

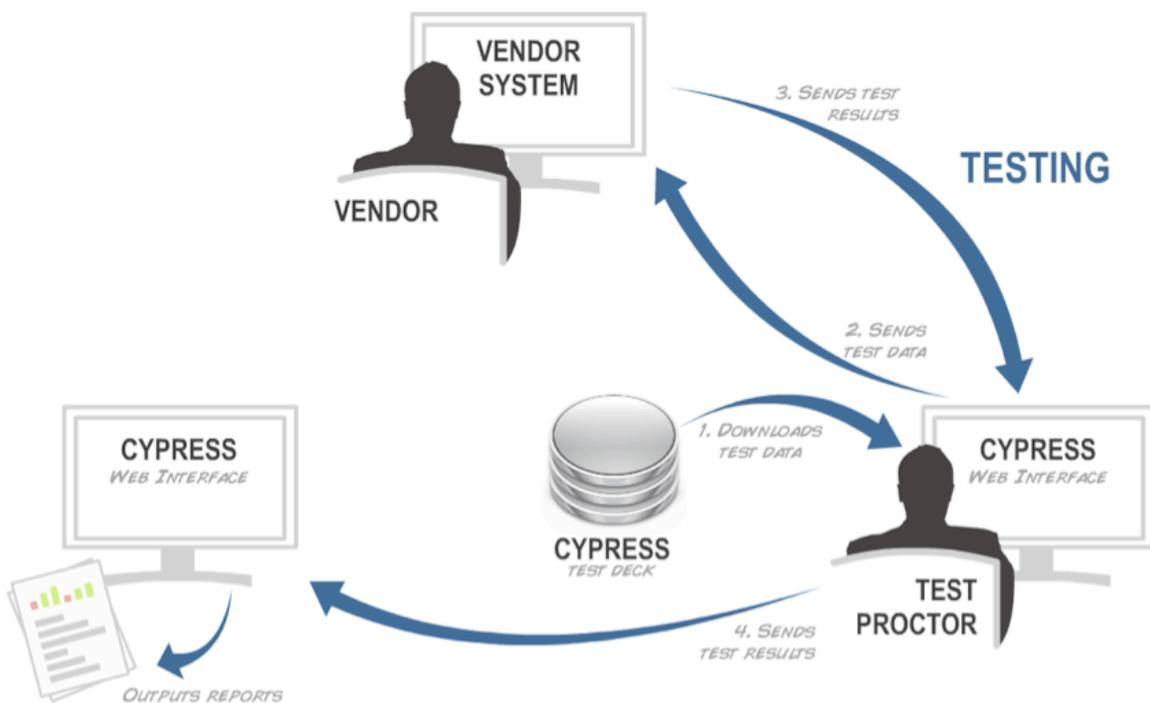
- Cypress – A software-testing tool developed by The MITRE Corporation and funded by the Office of the National Coordinator for Health Information Technology (ONC) to test the calculation, export and electronic submission of CQMs. The web site for the project is <http://projectcypress.org/>.
- EHR Module – A component of an EHR System that only supports a subset of the CQM certification criteria contained in §170.314(c).

- EHR System – A complete EHR that is capable of all three of the CQM certification criteria contained in §170.314(c).
- EHR Technology – This term can refer to either an EHR System or an EHR Module in situations where the distinction between the two is not relevant, or the topic being discussed is common to both types.
- Gold Source Scorecard – The expected results of the Gold Source Test Data for each of the Stage 2 CQMs specified in the Medicare and Medicaid Programs: Electronic Health Record Incentive Program – Stage 2.
- Gold Source Test Data – Cypress includes a set of patient test data that has been specifically developed for testing the Eligible Professional (EP) and Eligible Hospital (EH) CQMs.
- System Under Test (SUT) – The EHR technology that is being tested for compliance with the certification criteria contained in §170.314(c) and the procedures contained elsewhere in this document.

INFORMATIVE TEST DESCRIPTION

This section provides an informative description of how the test procedure is organized and conducted. It is not intended to provide normative statements of the certification requirements. This test procedure is based on the ONC approved and the National Institute of Standards and Technology (NIST) published procedure, version 1.1, for Stage 1 – 170.304(j) and augmented to include Cypress as a software tool for testing the accurate calculation, submission and degree of correctness of the CQMs. Figure 1 shows the expected general workflow of a test performed with Cypress.

Figure 1: Sample Authorized Testing Lab Workflow



This test procedure is centered on the open source software tool, Cypress. Cypress is capable of performing the following types of tests in support of CQM certification:

- XML Data conformance testing of the Quality Reporting Document Architecture (QRDA) Category 1 standard for individual patient-level data used for CQM calculation
- XML Data conformance testing of the Quality Reporting Document Architecture (QRDA) Category III standard for aggregate reporting of CQM calculation
- Accuracy calculation testing of the Meaningful Use Stage 2 Eligible Professional (EP) CQMs
- Accuracy calculation testing of the Meaningful Use Stage 2 Eligible Hospital (EH) CQMs

The principle mechanism for testing the accurate calculation of the clinical quality measures is the Cypress Gold Source Test Data. The Gold Source Test Data was designed to exercise all of the Stage 2 MU Eligible Professional (EP) and Eligible Hospital (EH) CQMs and is used to produce the Cypress Gold Source Scorecards of results by which EHR systems are evaluated.

Based on an EHR Vendor's software system capabilities, Cypress will provide either all or a subset of the Gold Source Test Data for this test procedure. It is anticipated that test scripts developed by ONC-Authorized Testing and Certification Bodies (ONC-ATCB) will determine the specifics on how the Cypress Gold Source Test Data is used and presented during a test. The Tester provides the Cypress Gold Standard Test Data to the Vendor for this procedure using one of the following methods:

- Manual entry - If manual entry is preferred by the vendor, Cypress can generate a formatted Hypertext Markup Language (HTML) page containing the test patient data for printing and human entry into the EHR SUT. It should be pointed out that manual entry of test patient data is considered the least desirable of all possible options for data entry due to a) the amount of time required to enter each patient (limiting the number of test patients that can be used and the rigor of the test); and b) the higher probability of data entry errors which could cause discrepancies in the calculated results generated by the SUT.
- Automated entry - Quality Reporting Document Architecture (QRDA) Category I XML format

This test procedure evaluates the capability of an EHR technology to calculate the CQMs (ambulatory or inpatient) for which it is being certified; and to electronically submit CQM data in accordance with the standard and implementation specified in §170.205(h) and (k). In addition to these capabilities, this test is intended to verify the degree of correctness of the implemented algorithms and resulting calculations of the quality measures based on the Cypress Gold Standard Test Data.

The test procedure is divided into two distinct phases to facilitate a workflow that supports performing a full test of the 170.314(c) criteria as well as a subset of the criteria (as may be the case for EHR module testing and some complete EHR system testing scenarios). Each phase focuses on a specific subset of the criteria outlined in 170.314(c). The specific criteria that would be validated or exercised by each phase are:

- Phase 1 – Verification of Capture and Export
- 170.314(c)(1)(i) Capture. [Only if manual entry or an electronic formats other than QRDA Category I is used to load test patient data.]
- 170.314(c)(1)(ii) Export.
- Phase 2 – Verification of Import, Calculate, and Electronic Submission
- 170.314(c)(2)(i) Import. [Optional for complete EHR systems]
- 170.314(c)(2)(ii) Calculate.
- 170.314(c)(3) Electronic submission.

PHASE 1: VERIFICATION OF CAPTURE AND EXPORT

The basic concept for Phase 1 of the certification testing is shown in Figure 2. The primary purpose of this phase is the verification of the EHR technologies' ability to export data in the proper format, and with the proper Quality Data Model (QDM) data elements. In this phase, Cypress produces static patient data for each of the CQMs that are to be tested, and exports the relevant patients in either QRDA Category I or HTML formats. This data is then loaded into the EHR SUT. The EHR is then commanded to export the patient test data in accordance with 170.314(c)(1)(ii) to produce a set of QRDA Category I files containing the proper elements from the QDM that are required to calculate the CQMs that are being tested. These QRDA files are loaded back into Cypress where they are tested for validity (valid QRDA Category I XML documents) and correctness (contain only the elements required to calculate the CQMs, and no more).

PHASE 2: VERIFICATION OF IMPORT, CALCULATE AND ELECTRONIC SUBMISSION

The basic concept for Phase 2 of the certification testing is shown in Figure 3. This test operates in two modes; for Eligible Professional (EP) CQM testing and Eligible Hospital (EH) testing. The EP testing will generate dynamic patient-level data with some level of randomization to guard against gamesmanship by EHR systems, but the initial plans for Cypress will include only static testing of the EH CQMs. This static EH testing will be enhanced and replaced over time with the eventual inclusion of dynamic EH CQM testing.

The purpose of this phase is verification that the EHR SUT can:

- a) Import properly formatted QRDA Category I documents (though complete EHR systems are exempt),
- b) Calculate the CQM results for the quality measures being certified, and
- c) Generate a properly formatted report that could be electronically submitted to the Centers for Medicare & Medicaid Services (CMS) using either QRDA Category I or QRDA Category III.

Figure 2: Verification of Capture and Export

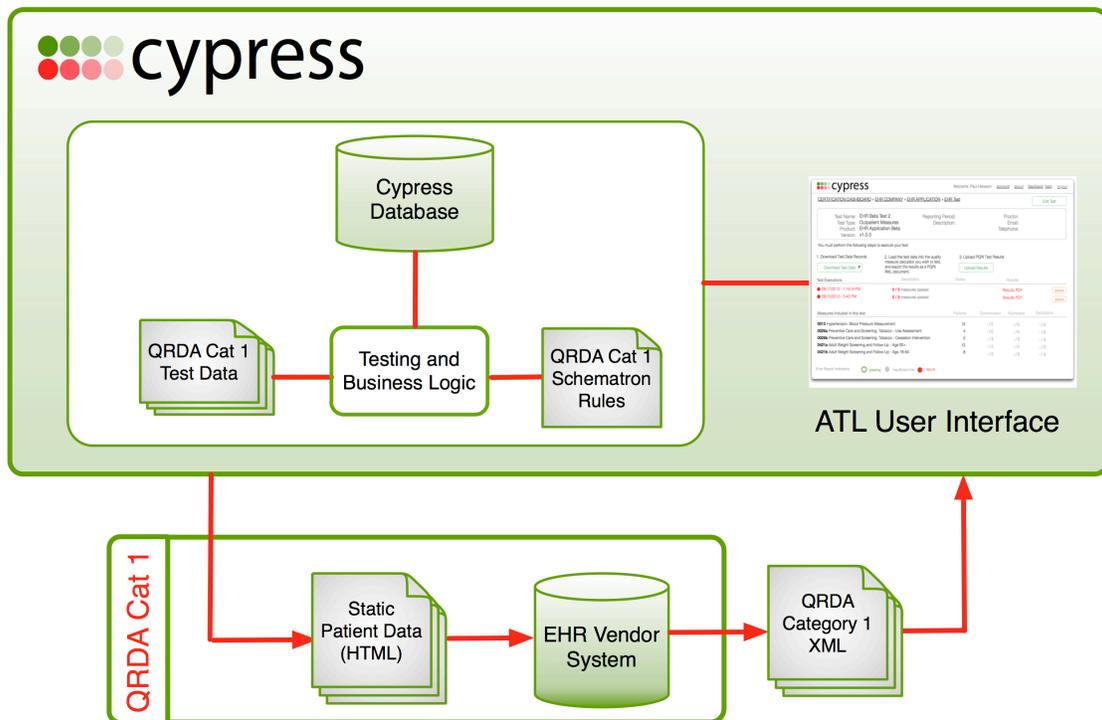
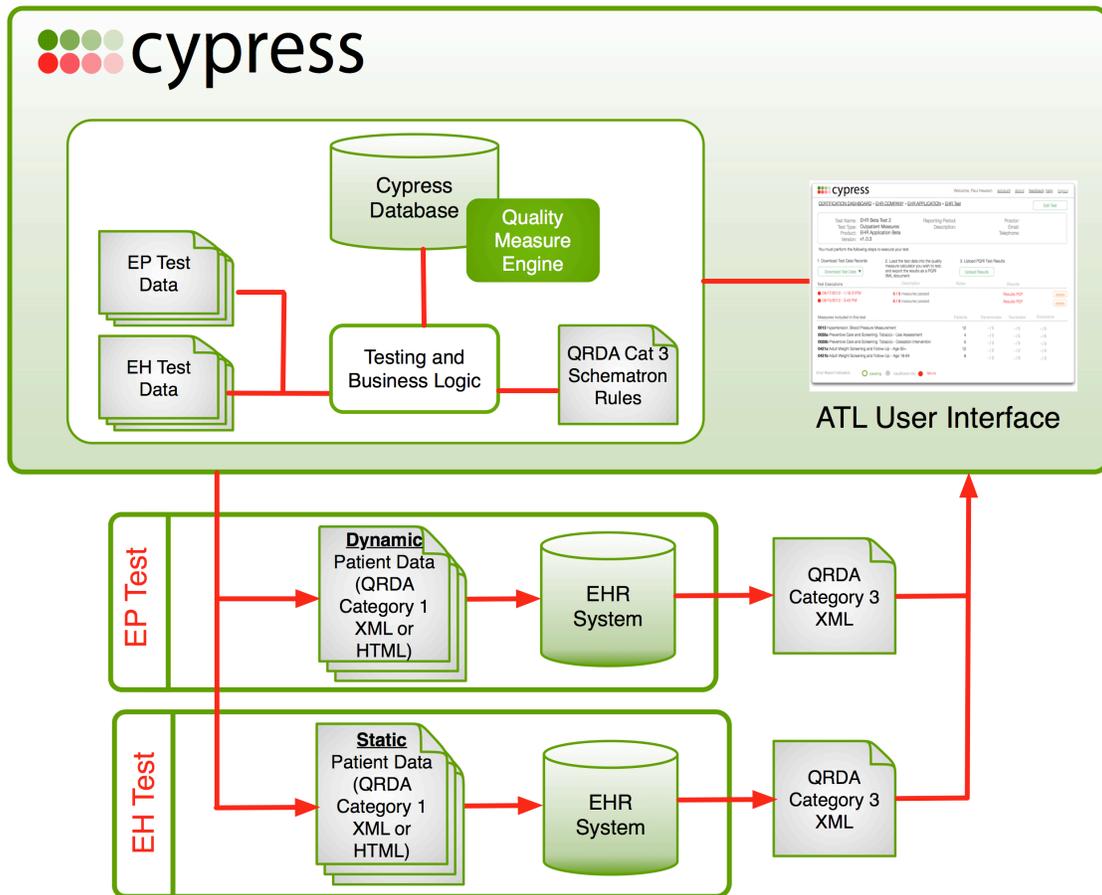


Figure 3: Verification of Import, Calculate and Electronic Submission



DETAILED TEST DESCRIPTION

Each phase of the test procedure is organized into four sections:

Prepare

Create the test data set for the EHR SUT – create the test patient data using Cypress for the CQMs on which the EHR system is expected to report.

- The Tester uses the Cypress user interface to add the EHR vendor and product being tested.
- The Tester creates a new test using the Cypress user interface and specifies the measures that will be tested, the format and the method to use for loading the test patients into the SUT.

Execute

Electronically generate clinical quality measure artifacts – evaluates the capability of the EHR SUT to electronically generate the proper CQM artifacts for the CQMs being certified.

- The Tester provides Cypress Gold Standard Test Data for the clinical quality measures that the EHR system will be tested in the format selected to the EHR vendor.
- The Vendor manually inputs or electronically imports the test data into their EHR system.
- The Tester examines the CQMs implemented in the EHR.
- The Tester validates that the proper CQM artifacts for the test being performed are electronically generated by the EHR SUT.

Submit

Electronically submit and verify generated CQM artifacts – evaluates the capability of EHRs to electronically submit a) calculated quality measures in accordance with the standard and implementation specifications; and b) exported patient data sufficient to allow external calculation.

- The Tester commands the EHR SUT to generate and electronically submit an aggregate report in the QRDA Category III format of the clinical quality measures calculated in the Execute test.
- The Tester commands the EHR SUT to generate and electronically submit the patient-level export in the QRDA Category I format for the clinical quality measures being tested.
- The Tester validates that the calculated clinical quality measures are submitted in accordance with the QRDA Category III standard and implementation specifications by uploading the QRDA Category III XML via the Cypress User Interface and the Cypress supplied XML Schema validation.
- The Tester validates that the exported patient-level CQM data are submitted in accordance with the QRDA Category I standard and implementation specifications by uploading the QRDA Category I XML via the Cypress User Interface and the Cypress supplied XML Schema validation.

Verify

Verify electronic and accurate generation of clinical quality measure artifacts – evaluates the capability to electronically and accurately generate CQM artifacts appropriate for each phase of the test procedure.

- After the Tester validates the submission of the QRDA Category III, the Tester evaluates and displays the accuracy of the submitted clinical quality measure results via the Cypress User Interface.
- The Tester generates a test artifact bundle containing all test data used for this test execution, all products generated and submitted by the EHR SUT, and any other additional notes or information that the Tester deems relevant into a single archive file that is cryptographically signed. This artifact bundle is what the Tester makes available to the EHR SUT.

REFERENCED STANDARDS

Standard. HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture.

Standard. Quality Reporting Document Architecture Category III, Implementation Guide for CDA Release 2.

Standard. Health Level Seven Clinical Document Architecture (CDA) Release 2, Continuity of Care Document (CCD).

Standard. ASTM E2369 Standard Specification for Continuity of Care Record and Adjunct to ASTM E2369.

NORMATIVE TEST PROCEDURES – PHASE 1 – VERIFICATION OF CAPTURE AND EXPORT

Derived Test Requirements

DTR170.314.c – 1.1: Create the Gold Standard test data set

DTR170.314.c – 1.2: Export patient data from the EHR SUT

DTR170.314.c – 1.3: Submit exported patient data

DTR170.314.c – 1.4: Verify validity and correctness of exported patient data

DTR170.314.c – 1.1: Create the Gold Standard test data set

Required Vendor Information

VE170.314.c – 1.1.01: Vendor shall provide sufficiently detailed information about the EHR SUT such that the setup may be recreated in the future. Examples would be: product version number, the name and version of any optional modules installed in the product at the time of the test, and the operating system (and version) on which the EHR SUT is running.

VE170.314.c – 1.1.02: Vendor shall identify the clinical quality measures for which their EHR system is being certified.

Required Test Procedure:

TE170.314.c – 1.1.01: Tester logs into the Cypress application and checks if the vendor of the EHR technology under test is listed on their Testing Dashboard. If the vendor is listed, testing proceeds to **TE170.314.c – 1.1.03**.

TE170.314.c – 1.1.02: Tester clicks on the “Add EHR Vendor” button and fills out the vendor information form shown in Figure 4, then clicks the “Create” button. The Tester is returned to the dashboard and the new vendor appears in the list (see Figure 5 for an example).

Figure 4: Create new vendor information form

cypress Welcome, Tim [account](#) [about](#) [feedback](#) [help](#) [logout](#)

[CERTIFICATION DASHBOARD](#) » CREATE NEW VENDOR

Vendor Information

* Vendor Name: EHR POC:

Vendor ID: Email:

Url: Phone:

Address: Fax:

State:

ZIP:

alternate POCs

Main EHR POC: Technical POC:

Email: Email:

Phone: Phone:

Press POC:

Email:

Phone:

Figure 5: New vendor displayed in dashboard

The screenshot shows the Cypress Certification Dashboard. At the top left is the Cypress logo. At the top right, it says "Welcome, Michael" followed by links for [account](#), [about](#), [feedback](#), [help](#), and [logout](#). Below the header, there are two buttons: "Master Patient List" and "Add EHR Vendor". A welcome message reads: "Welcome to Cypress! This is the Certification Dashboard that displays the names of the EHR vendors and the status of their products being tested. You can begin by adding an EHR vendor or simply explore the complete Cypress Test Deck by clicking on 'Master Patient List' above." Below this is a table with the following columns: "EHR VENDOR NAME", "PRODUCTS TESTED", "PASSING", "NOT PASSING", and "DATE OF LAST TEST". There is one row for "EHR Vendor Company" with "0 / 0 products" in the "PRODUCTS TESTED" column, "0 products" in the "PASSING" column, and "0 products" in the "NOT PASSING" column. A "delete" button is located to the right of the row. At the bottom, there are "Error Report Indicators" with three options: "passing" (green circle), "insufficient info" (grey circle), and "failing" (red circle).

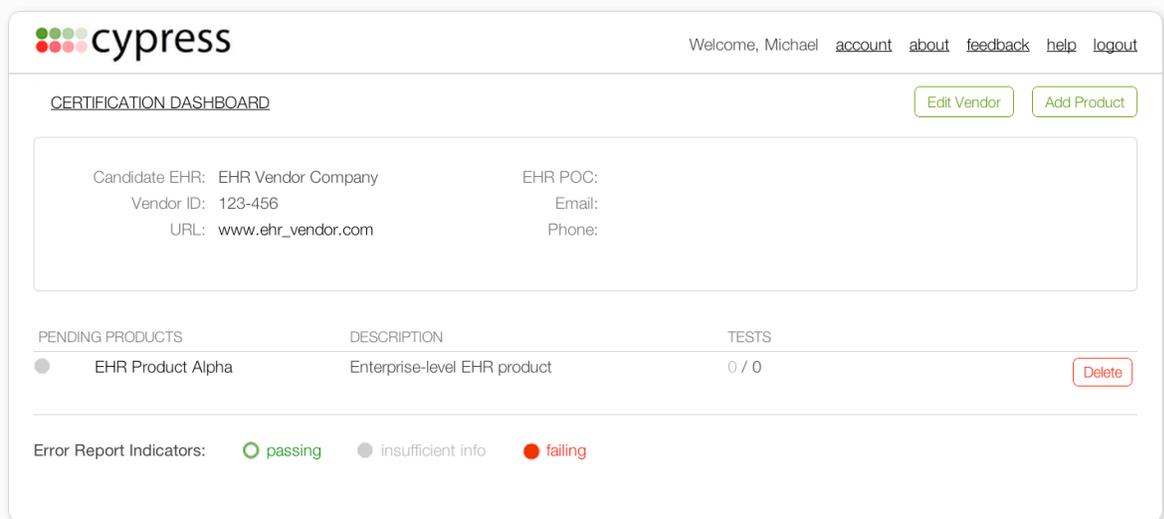
TE170.314.c – 1.1.03: Tester clicks on the EHR vendor whose product is under test and checks if the EHR product is listed on the page. If the product is listed, testing proceeds to **TE170.314.c – 1.1.05**.

TE170.314.c – 1.1.04: Tester clicks on the “Add Product” button and fills out the product information form shown in Figure 6. In the description field, enter the detailed information about the product provided in VE170.314.c – 1.1.01, then click the “Create” button. The Tester is returned to the vendor page and the new product appears in the list. An example vendor page with one product added is shown in Figure 7.

Figure 6: Create a new product form

The screenshot shows the "Create New Product" form in the Cypress dashboard. The breadcrumb trail is "CERTIFICATION DASHBOARD » EHR VENDOR COMPANY » CREATE NEW PRODUCT". The form is titled "Product Information" and contains three input fields: "Product Name:" (with a red asterisk), "Description:", and "Version:". A "Create" button is located at the bottom left of the form area.

Figure 7: Vendor with one product added



- TE170.314.c – 1.1.05: Tester clicks on the EHR product being tested on the vendor page and is presented with the product page which lists all of the tests that this Tester has created for this product. A sample of the product dashboard for a newly added product that does not have any defined tests is shown in Figure 8. Tester clicks on either of the “Add Test” buttons to begin a new test sequence. This begins a test creation wizard which allows the Tester to define the parameters for the test.
- Tester provides a name, description and test type (in this phase, select QRDA Category I) for the test using the form shown in Figure 9 and clicks the “Next” button.
 - For each CQM to be tested, the Tester selects all of the clinical quality measures that will be tested using the form shown in Figure 10 and clicks the “Done” button.
 - Tester is returned to the product dashboard with the newly created test listed under the heading “Incomplete Tests” (see Figure 11).
 - Tester clicks on the title of the one CQM Category 1 test to be executed and is displayed a screen similar to Figure 12.
 - In order to identify test records associated with those QRDA Category 1 CQM tests, Tester must then setup either an Eligible Hospital (EH) test or Eligible Professional (EP) test that is associated with the identical CQM(s) selected in step (b).
 - After setting up the respective EP or EH CQM tests, Tester is returned to the product dashboard with the newly created tests.

- g) In order to download the test records for manual entry for the QRDA Category 1 tests, Tester should click on the EP test or the EH test, and moves the mouse over the “Test Data” button and clicks on the mechanism and data format that will be used to download the test patients. At that point, the patients from either the EH or EP tests should be entered into the SUT as the inputs to the QRDA Category 1 tests.
- h) After the Tester chose one of the “Download ...” options, a dialog box will be displayed that will allow the zip file that contains the test data to be saved somewhere on the Tester’s computer.

TE170.314.c – 1.1.06: Tester provides the test data saved in TE170.314.c – 1.1.05(f) to the Vendor for import into the EHR SUT. The format of the test data will depend on the capabilities of the EHR SUT. The Cypress provided test data should not be loaded into the EHR SUT at this time.

Figure 8: Product dashboard with no tests

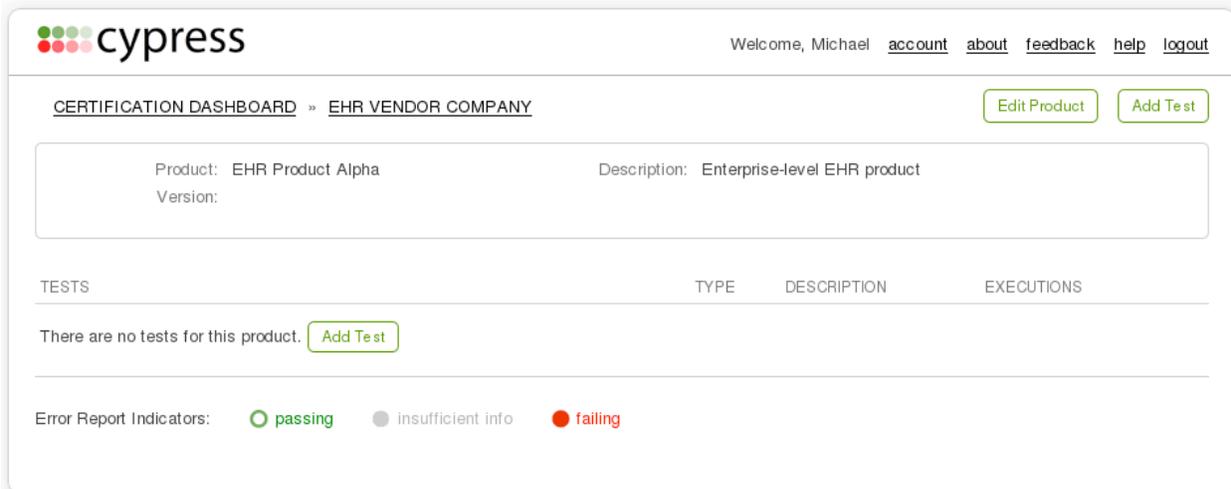


Figure 9: Create new test step 1 - Basic Information

cypress Welcome, Michael [account](#) [about](#) [feedback](#) [help](#) [logout](#)

[CERTIFICATION DASHBOARD](#) » [EHR VENDOR COMPANY](#) » [EHR PRODUCT ALPHA](#) » CREATE NEW TEST

Back Step 1 of 2 Next

Describe the test...

* Test Name:

Reporting Period: from 09/30/2010 to 12/30/2010

Description:

Test Type:

- Outpatient - to test quality measures for Eligible Professionals (EP)
- Inpatient - to test quality measures for Eligible Hospitals (EH)
- QRDA Category I - to test using the QRDA Category I format

Figure 10: Create new test step 2 - CQM selection

The screenshot shows the Cypress system interface for creating a new test. The breadcrumb trail is: CERTIFICATION DASHBOARD » TEST VENDOR » TEST PRODUCT » CREATE NEW TEST. The user is logged in as Rob. The current step is Step 2 of 2. The main instruction is: Identify at least one quality measure to test from the list of available measures for this product... There is a checkbox for "all quality measures" which is currently unchecked. A sidebar on the left lists various medical specialties, with "Cancer" selected and a count of "2". The main area displays a list of cancer-related quality measures with checkboxes:

- all Cancer measures
- 0384 - Oncology: Medical and Radiation – Pain Intensity Quantified
- 0385 - Colon Cancer: Chemotherapy for AJCC Stage III Colon Cancer Patients
- 0387 - Breast Cancer: Hormonal Therapy for Stage IC-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer
- 0389 - Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients

Figure 11: New test creation complete

The screenshot shows the Cypress Certification Dashboard for an EHR Vendor Company. The breadcrumb trail is "CERTIFICATION DASHBOARD » EHR VENDOR COMPANY". There are two buttons: "Edit Product" and "Add Test".

Product: EHR Product Alpha
 Version: v1.0
 Description: Enterprise-level EHR product

INCOMPLETE TESTS	TYPE	DESCRIPTION	EXECUTIONS
<input type="radio"/> EHR Alpha Test	QRDA Cat I	Testing EHR Product Alpha with latest code updates.	0

Delete

Error Report Indicators: passing insufficient info failing

Figure 12: Test dashboard with no test executions

The screenshot shows the Cypress Test Dashboard for a specific test. The breadcrumb trail is "CERTIFICATION DASHBOARD » EHR VENDOR COMPANY » EHR PRODUCT ALPHA". There is one button: "Edit Test".

Test Name: EHR Alpha Test
 Test Type: QRDA Cat 1
 Product: EHR Product Alpha
 Version: v1.0

Reporting Period: 09/30/2010 - 12/30/2010
 Description: Testing EHR Product Alpha with latest code updates.

Proctor: Michael Nosal
 Email: mnosal@mitre.org
 Telephone:

You must perform the following steps to execute your test:

1. Download Test Data
2. Load Test Data into your quality measure calculator
3. Upload Results

Notes:

TEST EXECUTIONS	DESCRIPTION	RESULTS
There are no test executions		

Error Report Indicators: passing insufficient info failing

DTR170.314.c – 1.2: Export patient data from the EHR SUT

Required Vendor Information

VE170.314.c – 1.2.01: Vendor shall identify the EHR function(s) that are available to export patient test data in QRDA Category I format.

Required Test Procedure:

TE170.314.c – 1.2.01: Tester provides test data from Cypress generated in **DTR170.314.c – 1.1** to the Vendor that is relevant to the CQMs that the EHR will be tested on in HTML format.

TE170.314.c – 1.2.02: The test data from the previous step is manually entered into the EHR SUT, based on the capabilities of the product being tested by re-purposing patient records used in the EP and/or EH import and calculate tests. The test patient generated by the QRDA Category I test itself and accessible from the download link on the QRDA Category I test page should not be used for the purposes of this test. The purpose of this change is to alleviate difficulties that have been encountered utilizing the generated QRDA Category I test record. Depending on the measures selected for the test the generated record can become excessively verbose and contain many conflicting data elements. By repurposing the existing EP and EH test records the SUT will be supplied with records that do not contain conflicting data elements while at the same time reducing the overall size of the data that will need to be entered into the system.

TE170.314.c – 1.2.03: Using the EHR function(s) identified in **VE170.314.c – 1.2.01**, the Vendor shall electronically export the patient test data in QRDA Category I format for the CQMs being tested while observed by the Tester and provide this data to the Tester. A single QRDA Category I document for each of the test patients that fall into the IPP for at least one of the CQMs being tested should be generated which contains the data for all of the CQMs under test.

DTR170.314.c – 1.3: Verify validity and correctness of exported patient data

Required Vendor Information

VE170.314.c – 1.3.01: The exported QRDA Category I documents generated and provided to the Tester in **TE170.314.c – 1.2.03**.

Required Test Procedure:

TE170.314.c – 1.3.01: Tester displays the Product Test dashboard page in Cypress (log in, click on vendor, click on product, and click on test name). For each of QRDA Category I files generated by the SUT the Tester will perform a QRDA Category I test

execution with the following procedure. The Tester clicks on the “Results” button. In the dialog that appears the Tester clicks on the “Browse...” button next to the “1. Results File” input box and selects the file received from the Vendor in **TE170.314.c – 1.2.03**, then clicks the “Upload” button (see Figure 13).

Figure 13: Upload test execution results

The screenshot shows the Cypress web application interface. At the top, the Cypress logo is on the left, and the user's name 'Welcome, Michael' with links for 'account', 'about', 'feedback', 'help', and 'logout' is on the right. Below the header, the breadcrumb navigation shows 'CERTIFICATION DASHBOARD > EHR VENDOR COMPANY > EHR PRODUCT ALPHA' and an 'Edit Test' button. The main content area displays test details: Test Name: EHR Alpha Test, Reporting Period: 09/30/2010 - 12/30/2010, Proctor: Michael Nosal, Test Type: QRDA Cat 1, Description: Testing EHR Product Alpha with latest code updates, Email: mnosal@mitre.org, Product: EHR Product Alpha, and Version: v1.0. Below this, a message states 'You must perform the following steps to' followed by '1. Download Test Data' and a 'Test Data' button. A 'Notes:' section is also present. An 'Upload Results' dialog box is open, showing a '1. Results File' with a 'Choose File' button and the filename '0041_Prevent...aSample.xml'. 'Upload' and 'Cancel' buttons are at the bottom of the dialog. Below the dialog, there is a table for 'TEST EXECUTIONS' with columns for 'DESCRIPTION' and 'RESULTS', and a note 'There are no test executions'. At the bottom, 'Error Report Indicators' are shown: a green circle for 'passing', a grey circle for 'insufficient info', and a red circle for 'failing'.

TE170.314.c – 1.3.02: Once the upload of the QRDA Category I documents is finished, validation will be performed on the uploaded documents. The Tester shall review any QRDA validation warnings or errors that are displayed at the top of the test details page. Examples of a test execution with validation errors can be seen in Figure 14 and Figure 15.

TE170.314.c – 1.3.03: The Tester downloads the Cypress test report by clicking the “Download” button at the top of the test details page, and selecting the “Report as PDF” option. The Tester should choose to save the generated PDF report in a location on their local system designated for the artifacts from this complete test (Phase 1 and Phase 2).

TE170.314.c – 1.3.04: The Tester shall collect all of the artifacts that resulted from testing this EHR system into the same location. This includes the following:

- Cypress test patient data provided to the Vendor in TE170.314.c – 1.1.06.
- The QRDA Category I export submitted by the Vendor in DTR170.314.c – 1.3.

- A copy of the manifest for the Cypress test tool instance that was used to generate the test data and create the test report. This file contains the version number of each of the subcomponents used by the particular Cypress instance. It is named CypressManifest.txt and is located in the root directory of the Cypress installation.
- The PDF report generated by Cypress in TE170.314.c – 1.3.03.
- Any additional files containing notes generated by the Tester during the execution of this test procedure.
- Any other files that the Tester deems relevant for this test execution.

TE170.314.c – 1.3.05: The Tester shall bundle the entire set of test artifacts collected in the previous step into a pkzip-compatible archive (zip archive) using utilities appropriate for the computer system the Tester is using.

Figure 14: Test execution with validation errors

The screenshot displays the Cypress web application interface. At the top left is the Cypress logo, and at the top right is the user greeting "Welcome, Michael" with links for "account", "about", "feedback", "help", and "logout". The main content area shows the breadcrumb "CERTIFICATION DASHBOARD > EHR.VENDOR.COMPANY > EHR.PRODUCT.ALPHA" and an "Edit Test" button. Below this is a summary box with test details: Test Name (EHR Alpha Test), Reporting Period (09/30/2010 - 12/30/2010), Proctor (Michael Nosal), Test Type (QRDA Cat 1), Description (Testing EHR Product Alpha with latest code updates), Product (EHR Product Alpha), Version (v1.0), and Email (mnosal@mitre.org). A section titled "You must perform the following steps to execute your test:" lists three steps: "1. Download Test Data" with a "Test Data" button, "2. Load Test Data into your quality measure calculator", and "3. Upload Results" with an "Upload Results" button. Below this is a "Notes:" section with a text input field and an "add note" button. A table titled "TEST EXECUTIONS" has columns for "TEST EXECUTIONS", "DESCRIPTION", and "RESULTS". It shows one execution on "2012-10-11 02:51:53 UTC" with a "Results" button. Underneath is the "TEST RESULTS" section with tabs for "Summary", "XML Errors", "XML Warnings", and "Content Inspection". The "Summary" tab is active, showing: "Test Date: 2012-10-11 02:51:53 UTC", "XML Validation Errors: 49", "Inspection ID: EHR Vendor Company", "XML Validation Warnings: 48", "Document Type: ** document type **", "Content Inspection Errors: ** content inspection errors **", and "Version: ** document version **".

Notes

In this test, a successful test execution is one in which there are no XML validation errors. XML validation warnings are allowed, and will not result in a test failure. However, the Tester should review the warnings generated and record any relevant observations that they can make about the reasons for the warnings in the **Notes** field on the Product Test details page.

As this procedure validates multiple QRDA Category I documents for a given test separately from each other the Tester should note any failed executions of this procedure as this would represent a failure of the test as a whole. Any subsequent testing to the SUT, as in a new set of QRDA Category I test records, should be performed using either a separate QRDA Category I test or by clearing the existing test executions from a given test before proceeding. Lastly, on the Product and Vendor pages a QRDA Category I test that is performed given these procedures may appear to be passing when it is not. This is due to the fact that a test is considered passing if the last test execution passed. These procedures deviate from that convention by considering all of the test executions to be taken as a whole, where one failed execution should represent a failed test. This is an interim process to address the issues that have been encountered using the generated QRDA Category I test record. This process will be automated in a future version of Cypress coupled with an updated test procedure anticipated for release at the end of April 2013.

Figure 15: Details of test execution with errors

Welcome, Michael [account](#) [about](#) [feedback](#) [help](#) [logout](#)

[CERTIFICATION DASHBOARD](#) » [EHR VENDOR COMPANY](#) » [EHR PRODUCT ALPHA](#) Edit Test

Test Name: EHR Alpha Test	Reporting Period: 09/30/2010 - 12/30/2010	Proctor: Michael Nosal
Test Type: QRDA Cat 1	Description: Testing EHR Product	Email: mnosal@mitre.org
Product: EHR Product Alpha	Alpha with latest code updates.	Telephone:
Version: v1.0		

You must perform the following steps to execute your test:

1. Download Test Data Test Data
2. Load Test Data into your quality measure calculator
3. Upload Results Upload Results

Notes:

add note

TEST EXECUTIONS	DESCRIPTION	RESULTS
2012-10-11 02:51:53 UTC		Results

TEST RESULTS

Summary XML Errors XML Warnings Content Inspection

Test Date: 2012-10-11 02:51:53 UTC	XML Validation Errors: 49
Inspection ID: EHR Vendor Company	XML Validation Warnings: 48
Document Type: ** document type **	Content Inspection Errors: ** content inspection errors **
Version: ** document version **	

Validation Notes:
Content discrepancies between patient record assigned to test and C32 under validation will be flagged as warnings. Patient summary content will be validated by visual inspection of the xml and using a stylesheet. UMLS validation errors will be visually inspected and verified. Neither content inspection warnings nor UMLS validation errors automatically determine PASS/FAIL status.

Vendor Generated XML

```
<?xml version="" encoding="" ?>
<?xml-stylesheet type="text/xsl" href="cda.xsl"?>
<!-- Disclaimer: The QRDA samples generated by the system are designed to provide a general idea about the
content, structure and parts of QRDA using hypothetical patient data; however, in this phase of the project,
the content of the QRDA sample documents may not have "clinically" consistent data. Additionally, in this
first phase of the project, some QRDA documents may not have all of the required Quality Data Elements and/or
may not be completely error-free (i.e. there may be QRDA schema conformance issues). -->
```

NORMATIVE TEST PROCEDURES – PHASE 2 – VERIFICATION OF IMPORT, CALCULATE AND ELECTRONIC SUBMISSION

Derived Test Requirements

- DTR170.314.c – 2.1: Create the Gold Standard test data set
- DTR170.314.c – 2.2: Electronically calculate clinical quality measures
- DTR170.314.c – 2.3: Electronically submit calculated clinical quality measures
- DTR170.314.c – 2.4: Verify electronic and accurate calculation of clinical quality measures

DTR170.314.c – 2.1: Create the Gold Standard test data set

Required Vendor Information

- VE170.314.c – 2.1.01: Vendor shall provide sufficiently detailed information about the EHR SUT such that the setup may be recreated in the future. Examples would be: product version number, the name and version of any optional modules installed in the product, and the operating system (and version) on which the EHR SUT is running.
- VE170.314.c – 2.1.02: Vendor shall identify the clinical quality measures for which their EHR system is being certified.

Required Test Procedure:

- TE170.314.c – 2.1.01: Tester logs into the Cypress application and checks if the vendor of the EHR technology under test is listed on their Testing Dashboard. If the vendor is listed, testing proceeds to **TE170.314.c – 2.1.03**.
- TE170.314.c – 2.1.02: Tester clicks on the “Add EHR Vendor” button and fills out the vendor information form shown in Figure 4, then clicks the “Create” button. The Tester is returned to the dashboard and the new vendor appears in the list (see Figure 5 for an example).
- TE170.314.c – 2.1.03: Tester clicks on the EHR vendor whose product is under test and checks if the EHR product is listed on the page. If the product is listed, testing proceeds to **TE170.314.c – 2.1.05**.
- TE170.314.c – 2.1.04: Tester clicks on the “Add Product” button and fills out the product information form shown in Figure 6. In the description field, enter the detailed information about the product provided in **VE170.314.c – 2.1.01**, then click the “Create” button. The Tester is returned to the vendor page and the new product appears in the list. An example vendor page with one product added is shown in Figure 7.
- TE170.314.c – 2.1.05: Tester clicks on the EHR product and is presented with the product page which lists all of the tests that this Tester has created for this product. A sample of the product dashboard for a newly added product that does not have any defined

tests is shown in Figure 8. Tester clicks on either of the “Add Test” buttons to begin a new test sequence. This begins a test creation wizard, which allows the Tester to define the parameters for the test.

- a) Tester provides a name, description and test type (in this phase, select either Inpatient or Outpatient depending on whether the SUT is being certified against EH or EP CQMs respectively) for the test and clicks the “Next” button.
- b) Tester selects all of the clinical quality measures that will be tested using the form shown in Figure 10 and clicks the “Done” button.
- c) Tester is returned to the product dashboard with the newly created test listed under the heading “Incomplete Tests” (see Figure 11).
- d) Tester clicks on the title of the test to be executed and is displayed a screen similar to Figure 12.
- e) Tester moves the mouse over the “Test Data” button and clicks on the mechanism and data format that will be used to load the test patients into the SUT.
- f) If the Tester chose one of the “Download ...” options, a dialog box will be displayed that will allow the zip file that contains the test data to be saved somewhere on the Tester’s computer.

TE170.314.c – 2.1.06: Tester provides the test data saved in TE170.314.c – 2.1.05(f) to the Vendor for import into the EHR SUT. The format of the test data will depend on the capabilities of the EHR SUT. The Cypress provided test data should not be loaded into the EHR SUT at this time.

DTR170.314.c – 2.2: Electronically calculate CQMs

Required Vendor Information

VE170.314.c – 2.2.01: Vendor shall import the Cypress Gold Standard test data supplied by Tester.

VE170.314.c – 2.2.02: Vendor shall describe the calculations for the specified clinical quality measures for which the EHR product is to be tested.

VE170.314.c – 2.2.03: Vendor shall identify the EHR function(s) that are available to: 1) electronically calculate the CMS clinical quality measures 2) electronically submit calculated clinical quality measures.

VE170.314.c – 2.2.04: Using the EHR function(s), the Vendor shall electronically calculate the specified clinical quality measures while observed by the Tester.

Required Test Procedure:

TE170.314.c – 2.2.01: Tester provides test data from Cypress generated in **DTR170.314c – 2.1** to the Vendor that will assess the clinical quality measures that the EHR will be tested on in QRDA Category I, and/or HTML format.

TE170.314c – 2.2.02: The Vendor will electronically import or manually enter the test data from the previous step into the EHR SUT, based on the capabilities of the product being tested. An EHR module must use the electronic import of test data in QRDA Category I format.

TE170.314c – 2.2.03: Using the EHR functions identified in **VE170.314.c – 2.2.03**, the vendor shall electronically calculate the CQMs that are being tested.

TE170.314.c – 2.2.02: Using the Inspection Test Guide below, Tester shall verify that the clinical quality measures are electronically calculated in **VE170.314.c – 2.2.04**.

Inspection Test Guide

IN170.314.c – 2.2.01: Using the specified clinical quality measures, Tester shall verify that these clinical quality measures are calculated as described by the Vendor in **VE170.314.c – 2.2.02**.

DTR170.314.c – 2.3: Verify electronic and accurate calculation of CQMs

Required Vendor Information

VE170.314.c – 2.3.01: The electronically submitted QRDA Category I and Category III quality measure reports generated in **DTR170.314.c–2.2**.

Required Test Procedure:

TE170.314.c – 2.3.01: Tester displays the Product Test dashboard page in Cypress (log in, click on vendor, click on product, and click on test name). Tester then clicks on the “Results” button. In the dialog that appears the Tester clicks on the “Browse...” button next to the “1. Results File” input box and selects the file received from the Vendor in **VE170.314.c – 2.3.01**, then clicks the “Upload” button (see Figure 13).

TE170.314.c – 2.3.02: Once the upload of the QRDA is finished, validation will be performed on the uploaded documents. The Tester shall review any QRDA validation warnings or errors that are displayed at the top of the test details page. Examples of a test execution with validation errors can be seen in Figure 14 and Figure 15.

TE170.314.c – 2.3.03: The Tester reviews the Cypress test details page (see Figure 16), which will display a dashboard of the denominator, numerator, and exclusions for each tested CQM. The values are displayed in the form **x / y** where **x** is the reported value obtained from the EHR SUT and **y** is the value Cypress expects based on the test data created for this particular test. The CQM for which the reported numerator, denominator, and exclusion values match the expected values are listed under the heading of “PASSING MEASURES.” If there are any

discrepancies between the reported values and the expected values, the affected CQM will be listed under the heading of “FAILING MEASURES” and the reported values that differ will be highlighted in a red and bold font. *Cypress is only capable of validating the correct calculation of CQMs for reports submitted in the QRDA Category III format. QRDA Category I formatted reports will be checked for validity only.*

Figure 16: Comparison of SUT calculated results against expected results

Test Name: EP Measure Test 1
 Test Type: EP
 Product: asdfasdf
 Version:

Reporting Period: 10/01/2010 - 01/01/2011
 Description:

Proctor: ff
 Email: bobd@mitre.org
 Telephone:

You must perform the following steps to execute your test:

1. Download Test Data

Test Data

2. Load Test Data into your quality
measure calculator

3. Upload Results

Upload Results

Notes:

add note

TEST EXECUTIONS

DESCRIPTION

RESULTS

2012-10-12 21:02:25 UTC

Results

TEST RESULTS

PASSING MEASURES

MEASURES INCLUDED IN THIS TEST	PATIENTS	DENOMINATOR	DEN.		NUM.	
			EXCLUSIONS	NUMERATOR	EXCLUSIONS	EXCEPTIONS
Diabetes: Foot Exam	1/1	1 / 1	- /	1 / 1	- /	- /
Diabetes: Urine Protein Screening	1/1	1 / 1	- /	1 / 1	- /	- /
Colon Cancer: Chemotherapy for AJCC Stage III Colon Cancer Patients	0/0	0 / 0	- /	0 / 0	- /	- /
Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients	0/0	0 / 0	- /	0 / 0	- /	- /
Breast Cancer: Hormonal Therapy for Stage IC-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer	0/0	0 / 0	- /	0 / 0	- /	- /
ADE Prevention and Monitoring: Warfarin Time in Therapeutic Range	0/0	- /	- /	0 / 0	- /	- /
Use of Appropriate Medications for Asthma - Population 1	1/1	1 / 1	- /	1 / 1	- /	- /
Use of Appropriate Medications for Asthma - Population 2	0/0	0 / 0	- /	0 / 0	- /	- /
Use of Appropriate Medications for Asthma - Population 3	1/1	1 / 1	- /	1 / 1	- /	- /
Use of Appropriate Medications for Asthma - Population 4	0/0	0 / 0	- /	0 / 0	- /	- /
Use of Appropriate Medications for Asthma - Population 5	0/0	0 / 0	- /	0 / 0	- /	- /
Diabetes: Eye Exam	1/1	1 / 1	- /	1 / 1	- /	- /

FAILING MEASURES

MEASURES INCLUDED IN THIS TEST	PATIENTS	DENOMINATOR	DEN.		NUM.	
			EXCLUSIONS	NUMERATOR	EXCLUSIONS	EXCEPTIONS
Colorectal Cancer Screening	1/2	2 / 1	- /	1 / 1	- /	- /
Breast Cancer Screening	0/1	1 / 0	- /	0 / 0	- /	- /
Cervical Cancer Screening	1/2	2 / 1	- /	0 / 0	- /	- /

Error Report Indicators: ○ passing ● insufficient info ● failing

TE170.314.c – 2.3.04: The Tester downloads the Cypress test report by clicking the “Download” button at the top of the test details page, and selecting the “Report as PDF” option. The Tester should choose to save the generated PDF report in a location on their local system designated for the artifacts from this complete test (Phase 1 and Phase 2).

TE170.314.c – 2.3.05: The Tester shall collect all of the artifacts that resulted from testing this EHR system into the same location. This includes the following:

- Cypress test patient data provided to the Vendor in **TE170.314.c – 2.1.06**.
- The QRDA Category I and/or Category III reports submitted by the Vendor in **VE170.314.c – 2.3.01**.
- A copy of the manifest for the Cypress test tool instance that was used to generate the test data and created the test report. This file contains the version number of each of the subcomponents used by the particular Cypress instance. It is named **CypressManifest.txt** and is located in the root directory of the Cypress installation.
- The PDF report generated by Cypress in **TE170.314.c – 2.3.04**.
- Any additional files containing notes generated by the Tester during the execution of this test procedure.
- Any other files that the Tester deems relevant for this test execution.

TE170.314.c – 2.3.06: The Tester shall bundle the entire set of test artifacts collected in the previous step into a pkzip-compatible archive (zip archive) using utilities appropriate for the computer system the Tester is using.

Notes

In this phase, the criteria used to determine a successful test outcome depends on whether the EHR product is being certified against the EP CQMs or the EH CQMs.

For EP CQMs, a successful test outcome is one in which the following conditions are true:

1. There were no XML validation errors in neither the QRDA Category I submitted data nor the QRDA Category III submitted data.
2. All of the CQM results calculated and submitted by the EHR SUT exactly match the values that Cypress was expecting.

For EH CQMs, a successful test outcome is one in which the following conditions are true:

1. There were no XML validation errors in neither the QRDA Category I submitted data nor the QRDA Category III submitted data.
2. All of the CQM results calculated and submitted by the EHR SUT for discrete measures exactly match the values that Cypress was expecting.

3. The CQM results calculated and submitted by the EHR SUT for continuous variable tests are within a defined delta of the value that Cypress was expecting.

For both types of EHR technologies, it is acceptable for there to be XML validation warnings that are generated by Cypress' validation process. These warnings will not constitute a test failure. However, the Tester should review the warnings generated and record any relevant observations that they can make about the reasons for the warnings in the Notes field on the Product Test details page.

ACRONYMS

ONC-ACB	ONC Authorized Certification Body
ONC-ATCB	ONC Authorized Testing and Certification Body
ASTM	American Society for Testing and Materials
CAH	Critical Access Hospital
CCHIT	Certification Commission for Healthcare Information Technology
CCR	Continuity of Care Record
CMS	Centers for Medicare & Medicaid Services
CQM	Clinical Quality Measures
EH	Eligible Hospital
EHR	Electronic Health Record
EP	Eligible Professional
GUI	Graphical User Interface
HITSP	Health Information Technology Standards Panel
HL7	Health Level Seven
HTML	Hypertext Markup Language
MU	Meaningful Use
NIST	National Institute of Standards and Technology
NQF	National Quality Forum
ONC	Office of the National Coordinator for Health Information Technology
QDM	Quality Data Model
QRDA	Quality Reporting Document Architecture
SUT	System Under Test
XML	Extensible Markup Language
XSD	XML Schema Document

Document History

Version Number	Description	Date
1.0	Released for public comment	November 2, 2012
1.1	Delivered for National Coordinator Approval	December 4, 2012
1.2	Posted Approved Test Procedure	December 14, 2012
1.3	Updated Test Procedure for the “Capture and Export” tests to re-purpose the patient records from the “Import and Calculate” tests to reduce burden on data entry	March 21, 2013