# 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 document[1] 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 Program[2], 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.

[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.

(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 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.

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

## 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 automated XML Data conformance testing 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. This procedure calls for the trained Tester to perform a visual inspection of the data presented by the EHR vendor to Cypress to validate reasonable data is present in the syntactically valid data for calculating each CQM the EHR system is being tested for.

- 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.

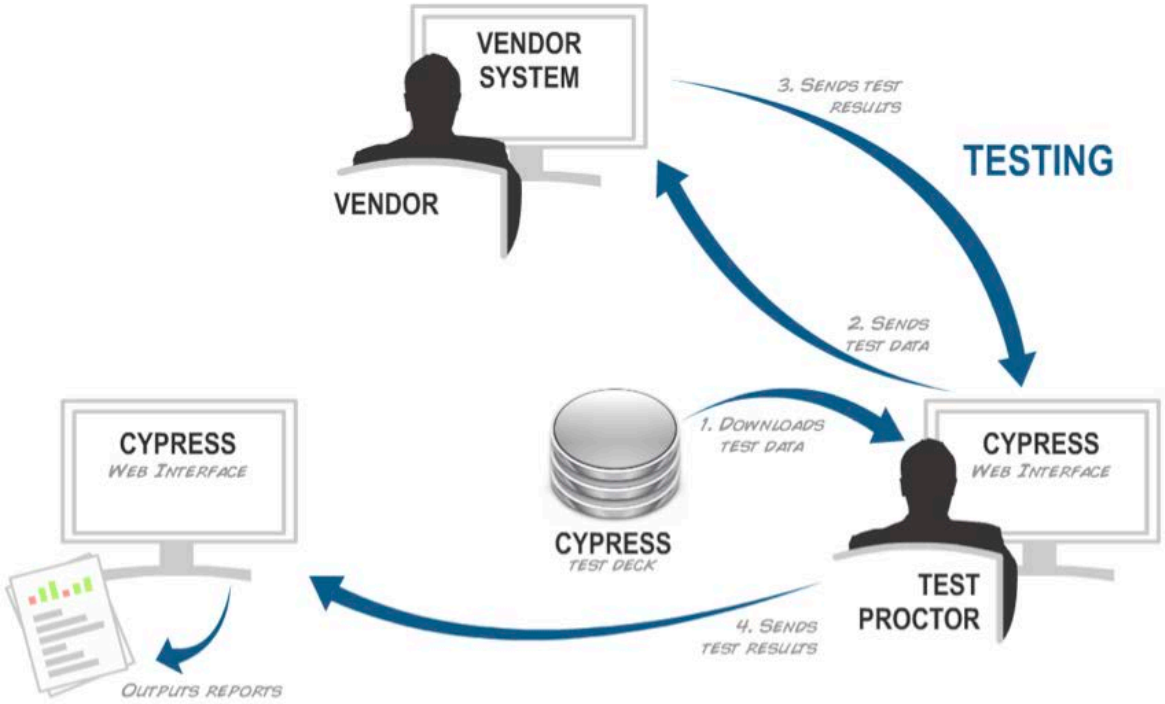
A number of terms are used in this test plan. This section enumerates those terms and defines how they are used in the context of this document.

- 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 test procedure for Stage 2 under 170.314.(c)(1) and 170.314.(c)(3), and has been 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 Import, Calculate, and Electronic Submission
- 170.314(c)(2)(i) Import. [Optional for complete EHR systems, and modular certification when certifying to c1, c2, and c3.]
- 170.314(c)(2)(ii) Calculate.
- 170.314(c)(3) Electronic submission.
- Phase 2 – 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 1: VERIFICATION OF IMPORT, CALCULATE AND ELECTRONIC SUBMISSION

The basic concept for Import, Calculate, and Electronic Submission certification testing is shown in Figure 2. This test operates in two modes; for Eligible Professional (EP) CQM testing and Eligible Hospital (EH) testing. Both types of tests will generate dynamic patient-level data with some level of randomization to guard against gamesmanship by EHR systems.

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

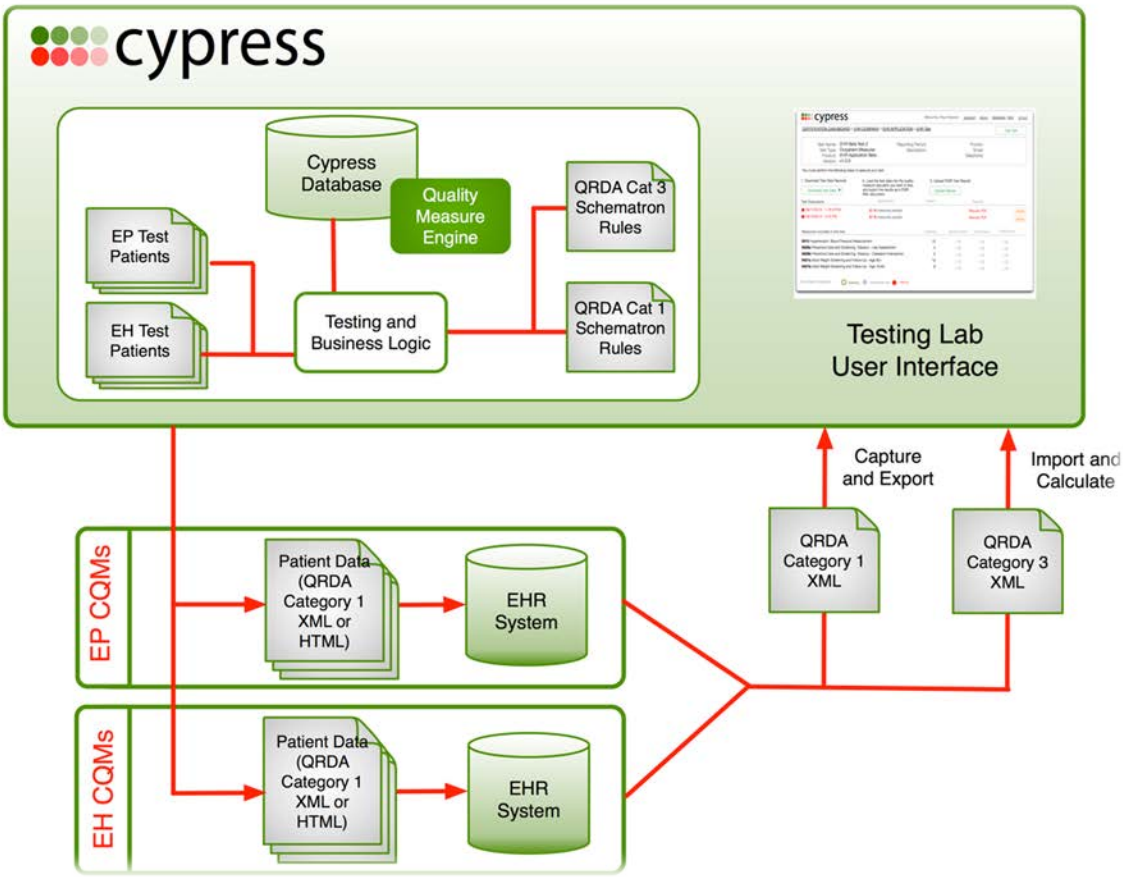
a) Import properly formatted QRDA Category I documents (though complete EHR systems are exempt from this requirement and manually enter the associated clinical data into the EHR system via the user interface).
b) Calculate the CQM results for the quality measures being certified
c) Generate a properly formatted report that could be electronically submitted to the Centers for Medicare & Medicaid Services (CMS) using QRDA Category III.

## PHASE 2: 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 patient data for each of the CQMs that are to be tested, and exports the relevant patients in either QRDA Category 1 XML or HTML formats. This data is then loaded into the EHR SUT. It is acceptable for an EHR SUT to "capture" QRDA Category 1 XML files in an automated way for their "capture and export" as long as the information is displayed in the appropriate places in the transaction system. For example, if a problem of the data type "problem list" is imported via a QRDA Category 1 XML file, it needs to be seen in the user interface in the problem list section. 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).

**Figure 2: Import and Calculate and Verification of Capture and Export testing in Cypress**



# 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 IMPORT, CALCULATE AND ELECTRONIC SUBMISSION

**Derived Test Requirements**

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

DTR170.314.c – 1.2: Electronically calculate and submit clinical quality measures

DTR170.314.c – 1.3: Verify electronic and accurate calculation of clinical quality measures

**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.

VE170.314.c – 1.1.03: The SUT must be able to report results based only on the records that have been supplied by the Tester from the Cypress tool for the purpose of CQM testing. This may be performed by associating the records with a single provider and reporting results only for said provider, or by another means. The Tester will be responsible for validating that the SUT has such capabilities and that reporting is performed based only on the records provided to the SUT and does not contain Protected Health Information (PHI).

Required Test Procedure:

TE170.314.c – 1.1.04: 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 – 1.1.05: Tester clicks on the “Add EHR Vendor” button and fills out the vendor information form shown in Figure 3, then clicks the “Create” button. The Tester is returned to the dashboard and the new vendor appears in the list (see Figure 4 for an example).

**Figure 3: Create new vendor information form**

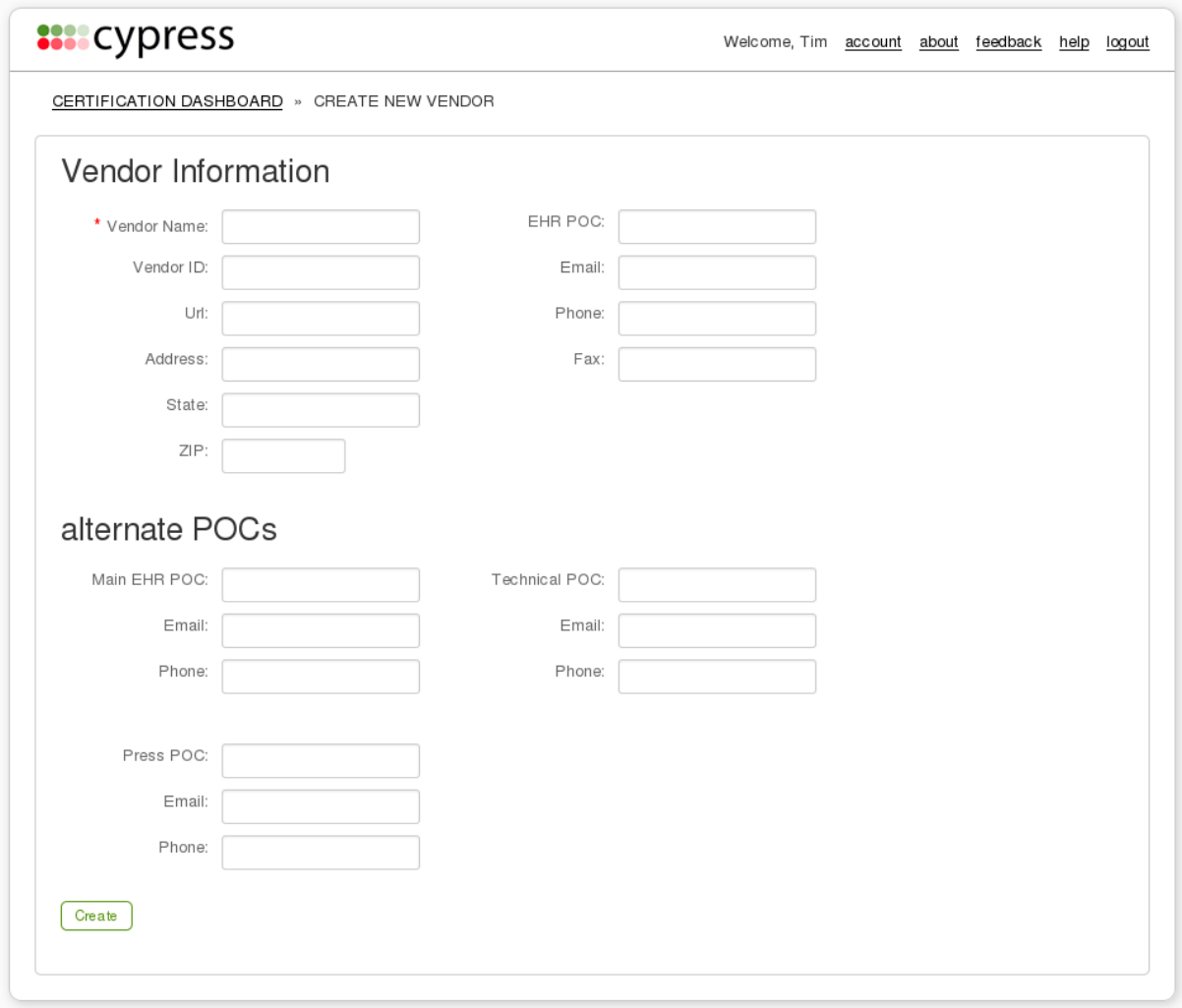
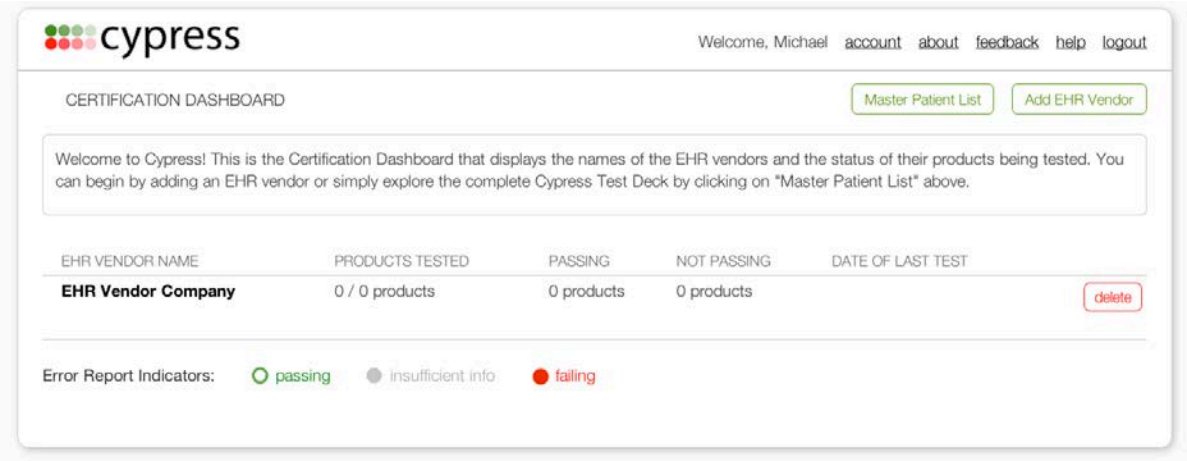


**Figure 4: New vendor displayed in dashboard**




TE170.314.c – 1.1.06: 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 – 1.1.07: 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 6.

**Figure 5: Create a new product form**

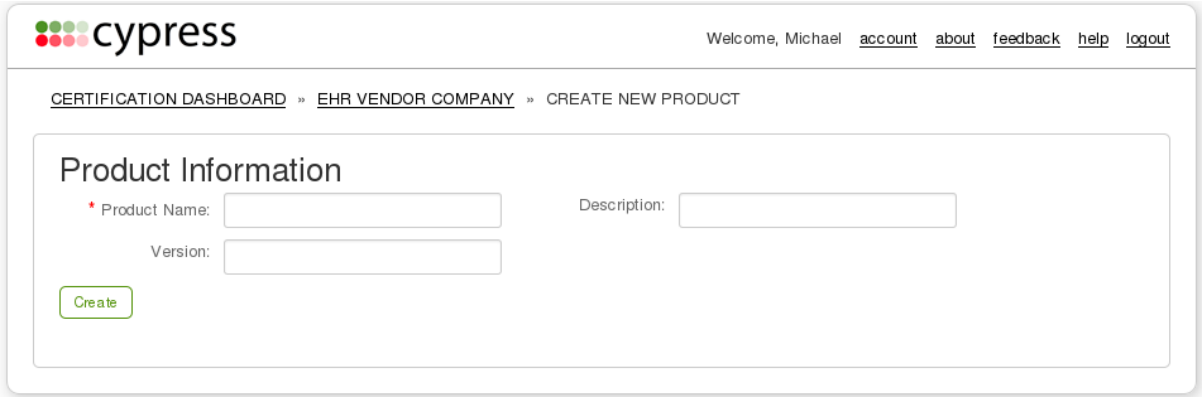
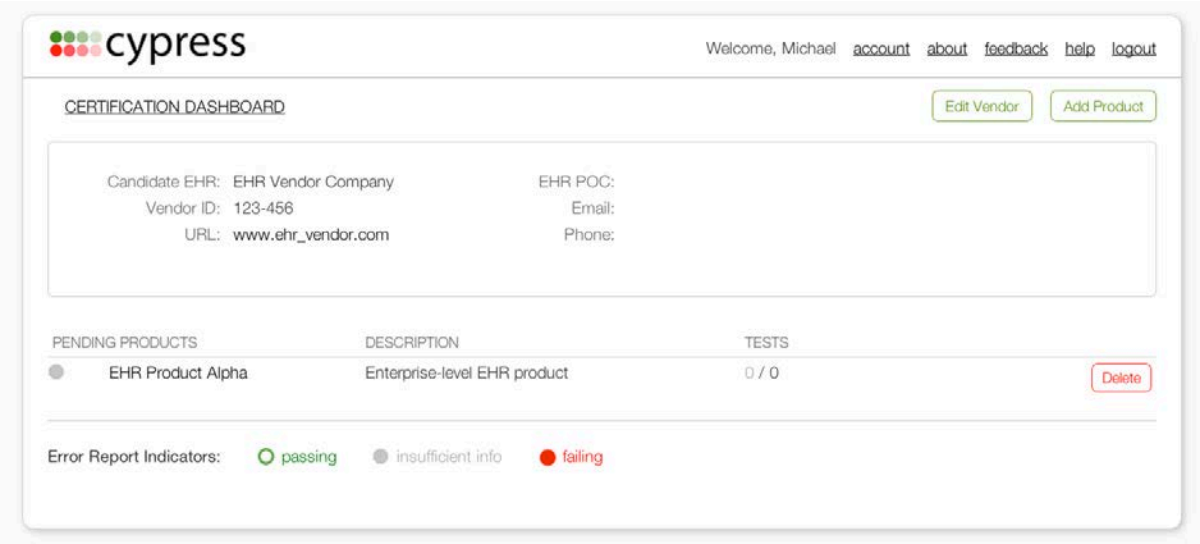


**Figure 6: Vendor with one product added**




TE170.314.c – 1.1.08: Tester clicks on the EHR product being tested on the vendor page and is presented with the product page. This page 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 7. Tester clicks on either of the "Add Test" buttons to begin a new test sequence. This begins a test creation wizard, which will allow the Tester to define the parameters for the test.

a) Tester provides a name, description and test type for the test using the form shown in Figure 8 and clicks the "Next" button.
b) 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 9 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 10).
d) Tester clicks on the title of the one test to be executed and is displayed a screen similar to Figure 11.
e) In order to download the test records for entry for the tests, Tester should click on the 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.

f) 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 – 1.1.09: 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 7: Product dashboard with no tests**

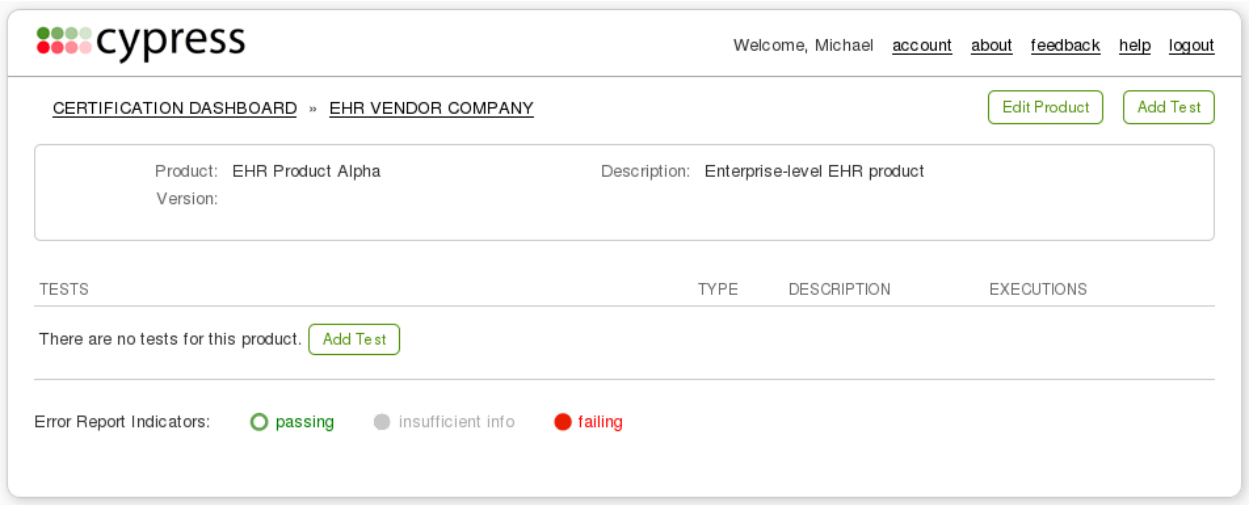



**Figure 8: Create new test step 1 - Basic Information**

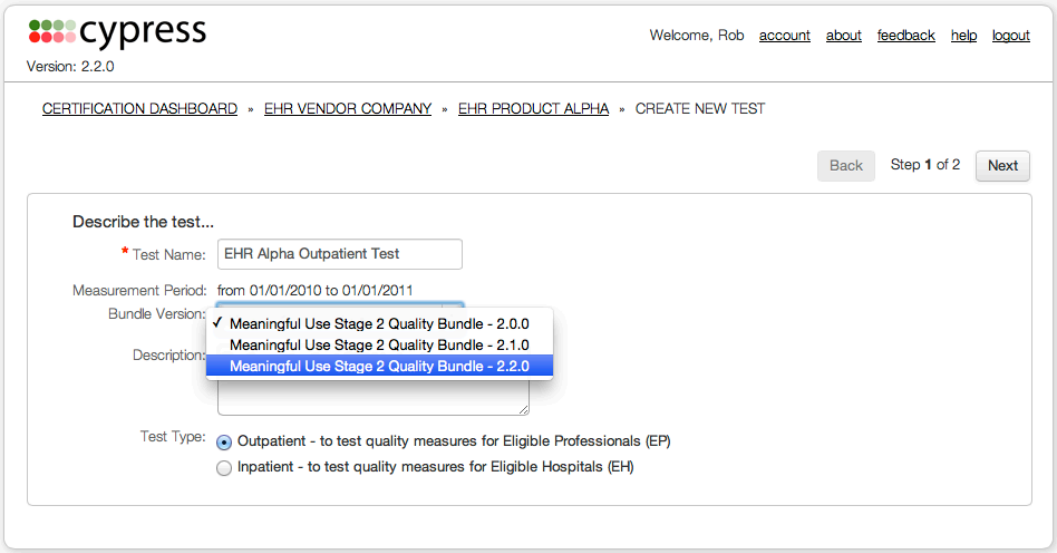


Figure 9: Create new test step 2 - CQM selection

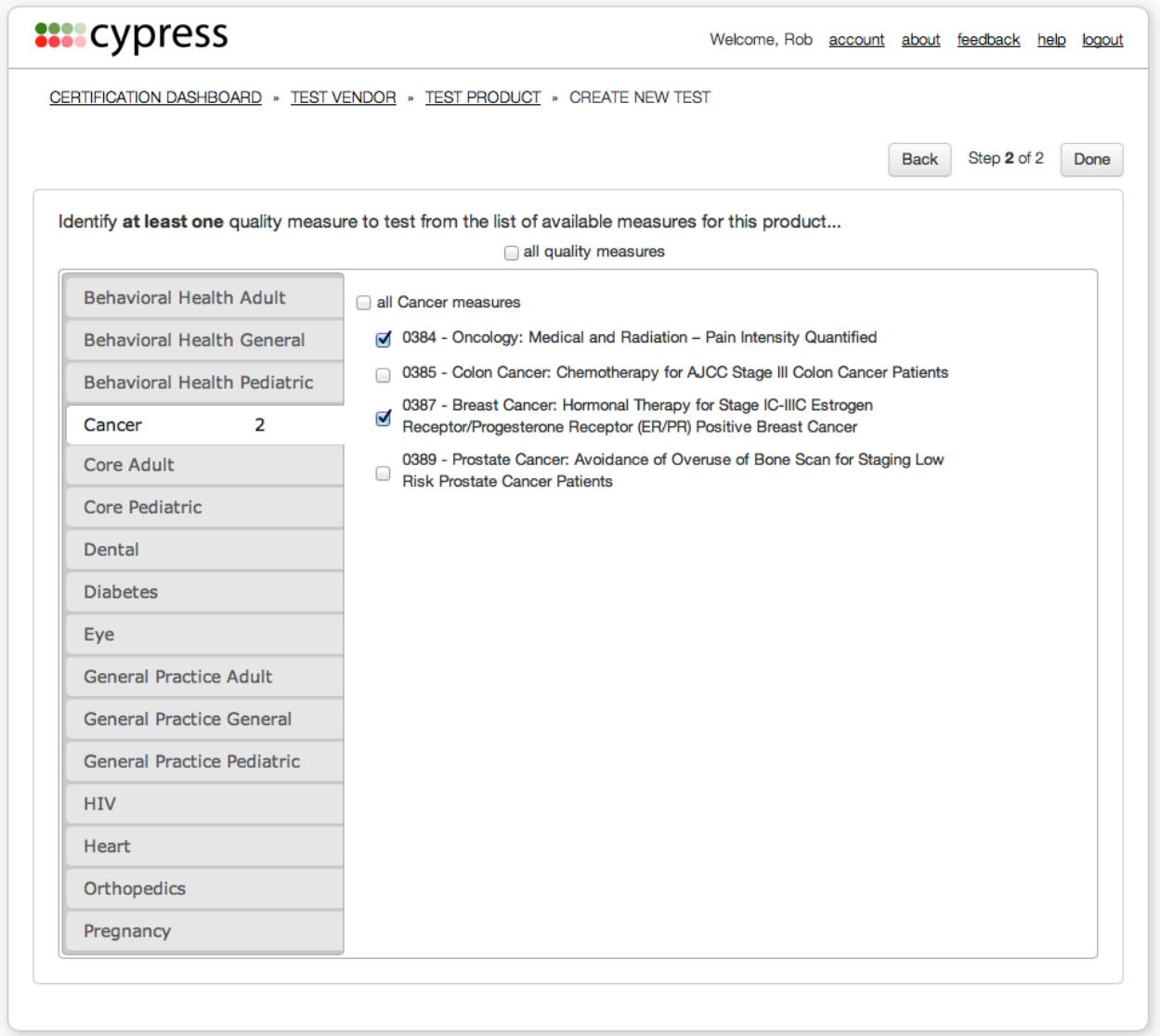


**Figure 10: New test creation complete**

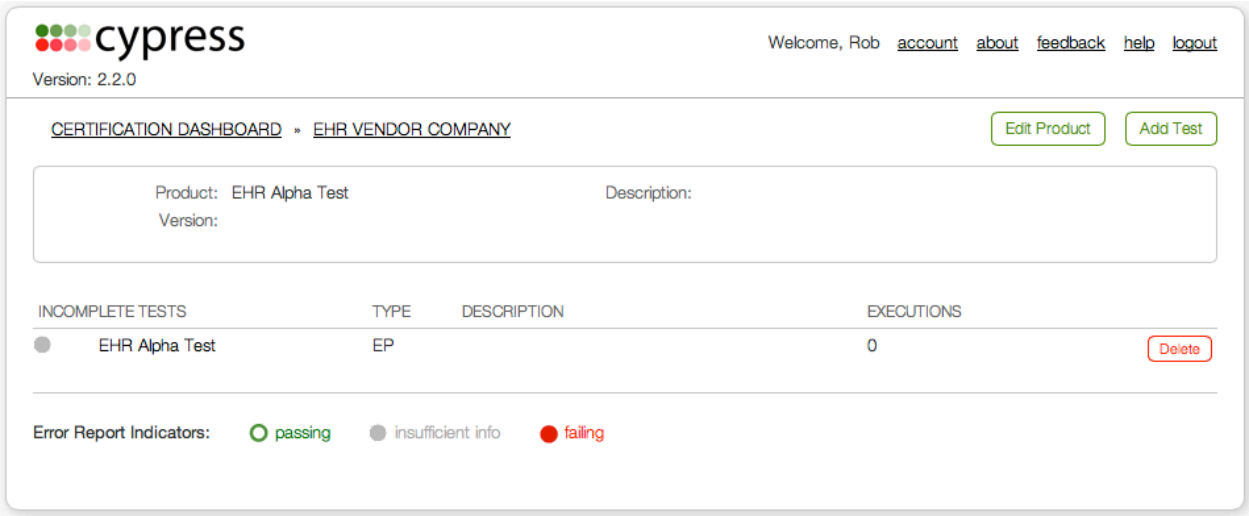
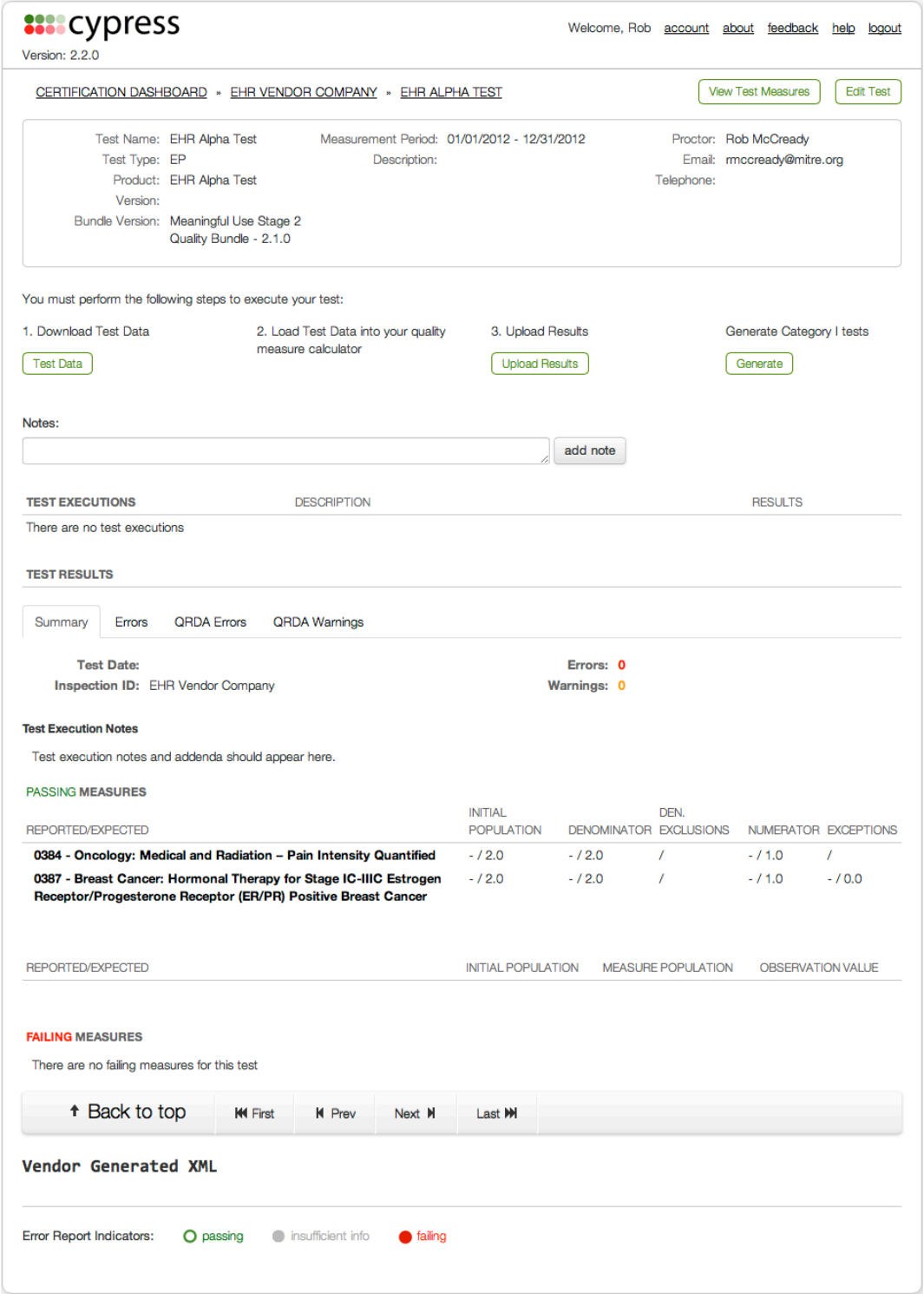


**Figure 11: Test dashboard with no test executions**



**DTR170.314.c – 1.2: Electronically calculate and submit CQMs**

Required Vendor Information

VE170.314.c – 1.2.01: Vendor shall import the Cypress Gold Standard test data supplied by Tester.

VE170.314.c – 1.2.02: Vendor shall describe the calculations for the specified clinical quality measures for which the EHR product is to be tested.

VE170.314.c – 1.2.03: 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 – 1.2.04: 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 – 1.2.05: Tester provides test data from Cypress generated in **DTR170.314c – 1.1** 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 – 1.2.06: 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 – 1.2.07: Using the EHR functions identified in **VE170.314.c – 1.2.03**, the vendor shall electronically calculate the CQMs that are being tested.

TE170.314.c – 1.2.08: Using the Inspection Test Guide below, Tester shall verify that the clinical quality measures are electronically calculated in **VE170.314.c – 1.2.04**.

Inspection Test Guide

IN170.314.c – 1.2.09: 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 – 1.2.02**.

**DTR170.314.c – 1.3: Verify electronic and accurate calculation of CQMs**

Required Vendor Information

VE170.314.c – 1.3.01: The electronically submitted Category III quality measure reports generated in **DTR170.314.c–1.2**.

Required Test Procedure:

TE170.314.c – 1.3.02: 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 – 1.3.01**, then clicks the "Upload" button (see Figure 13).

TE170.314.c – 1.3.03: 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 – 1.3.04: 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 12: 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: f f
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. EXCLUSIONS | NUMERATOR | NUM. 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. EXCLUSIONS | NUMERATOR | NUM. 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 – 1.3.05: 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 – 1.3.06: 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 III reports submitted by the Vendor in **VE170.314.c – 1.3.01**.
- The PDF report generated by Cypress in **TE170.314.c – 1.3.04**.
- 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 – 1.3.07: 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 both EP and 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 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.

## NORMATIVE TEST PROCEDURES – PHASE 2 – VERIFICATION OF CAPTURE AND EXPORT

**Derived Test Requirements**

DTR170.314.c – 2.1: Export patient data from the EHR SUT

DTR170.314.c – 2.2: Submit exported patient data

DTR170.314.c – 2.3: Verify validity and correctness of exported patient data

**DTR170.314.c – 2.1: Export patient data from the EHR SUT**

Required Vendor Information

VE170.314.c – 2.1.01: 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 – 2.1.02: The Tester visits the Cypress page previously setup for "Import and Calculate" tests and creates the Cypress QRDA Category I test reports by clicking the "Generate" button below the text "Generate Category I Tests". The tester has already provided the test data from Cypress generated in **DTR170.314c – 1.1** to the Vendor that is relevant to the CQMs that the EHR will be tested on. No additional data entry is needed if all records for the "Import and Calculate" tests were provided to the SUT. The purpose of this change in the test procedure is to utilizing a single unified set of patient records for testing both the QRDA Category III artifacts generated for the "Import and Calculate" tests, as well as the generated QRDA Category I test record for the "Capture and Export" tests.

TE170.314.c – 2.1.03: Using the EHR function(s) identified in **VE170.314.c – 1.1**, 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 zip file of all the QRDA Category I documents for each of the test patients that fall into the IPP for each of the CQMs being tested should be generated for each CQM. For the testing and certification of CQMs, a QRDA Category 1 XML file needs to be created per each patient created from Cypress for each CQM being tested. For each CQM being tested with Cypress, a single zip file with all the QRDA Category 1 XML files relevant for that particular CQM will be used to report the results of each CQMs under test. However, it is acceptable for an EHR SUT to include additional data from multiple CQMs within each QRDA Category 1 XML files with the testing and certification process. This ability to include data for multiple CQMs with each QRDA Category 1 XML file is consistent with the operational plans for reporting to the Centers for Medicare and Medicaid Services. EHR systems that can generate the QRDA Category 1 XML files relevant for each CQM, and EHR systems that can generate QRDA Category 1 XML for all CQMs at once may use either mode to upload their QRDA Category 1 XML data to Cypress. For EHR systems that can only generate QRDA Category 1 XML for all CQMs at once, Cypress will ignore additional clinical data for each CQM test, and will not fail EHR systems that

provide additional clinical data for CQMs not being tested, as long as the QRDA Category 1 XML file uploaded to Cypress is a valid QRDA Category 1 document.

**DTR170.314.c – 2.2: Submit exported patient data**

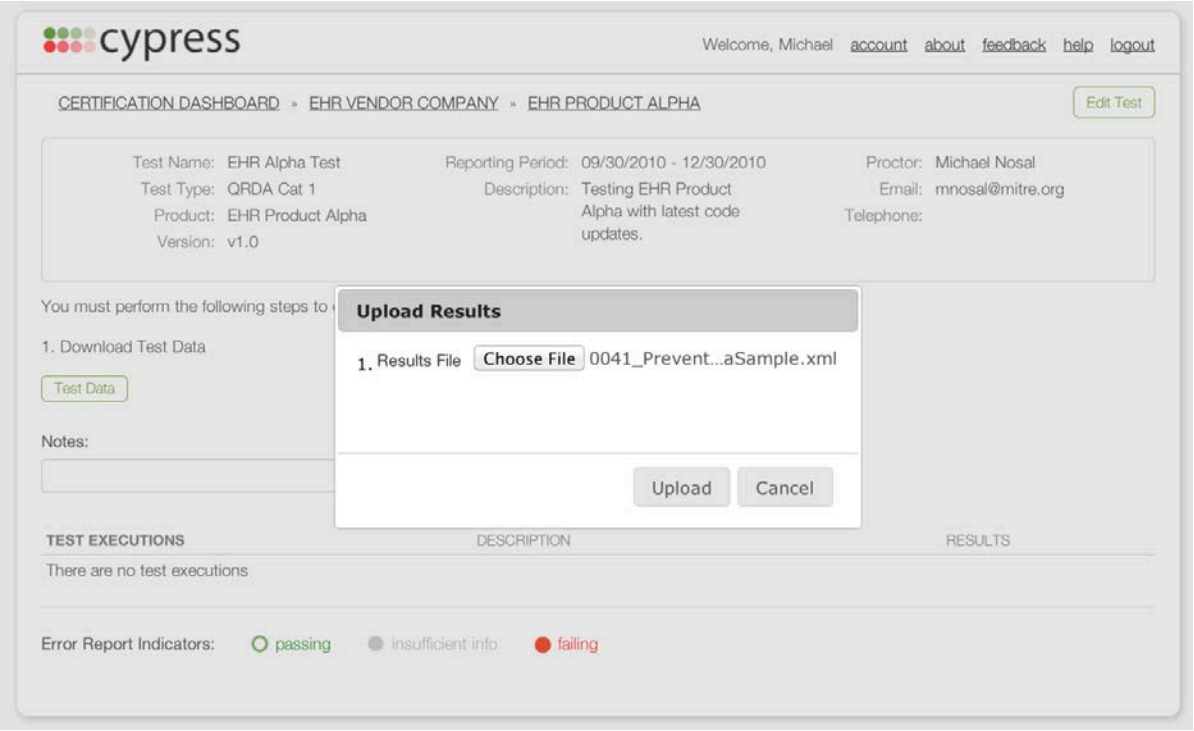
Required Vendor Information

VE170.314.c – 2.2.01: The exported QRDA Category I documents generated and provided to the Tester in **TE170.314.c – 2.1.03**.

Required Test Procedure:

TE170.314.c – 2.2.02: 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 zip 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 zip file of all QRDA Category I XML files received from the Vendor in **TE170.314.c – 2.1.03**, then clicks the "Upload" button (see Figure 13).

**Figure 12: Upload test execution results**




**DTR170.314.c – 2.3: Verify validity and correctness of exported patient data**

TE170.314.c – 2.3.01: Once the upload of the QRDA Category I documents is finished via a zip file, 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.

TE170.314.c – 2.3.02: If the Tester has selected a version of the measures less than v2.3 (see Figure 8: Create new test step 1) then the Tester must then perform a visual inspection of the data presented by the EHR vendor to Cypress to validate reasonable data is present in the syntactically valid data for calculating each CQM the EHR system is being tested for. This visual inspection process will be made with the "Cypress CQM Clinical Guidance Checklist" which will accompany the Cypress software. This document will detail the clinical artifacts that should be present in each patient record for each CQM. This additional visual inspection step is only required by the Tester to ensure that all clinical artifacts associated with a syntactically valid QRDA Category 1 XML file are present in the data presented

by the EHR vendor to the Tester when selecting versions of the measures less than v2.3. If the Tester has selected versions of the measures at or greater than or equal to v2.3, this visual inspection step is not required. This is because this additional check of the QRDA Category 1 XML is automated in software as part of Cypress v2.3 and higher.

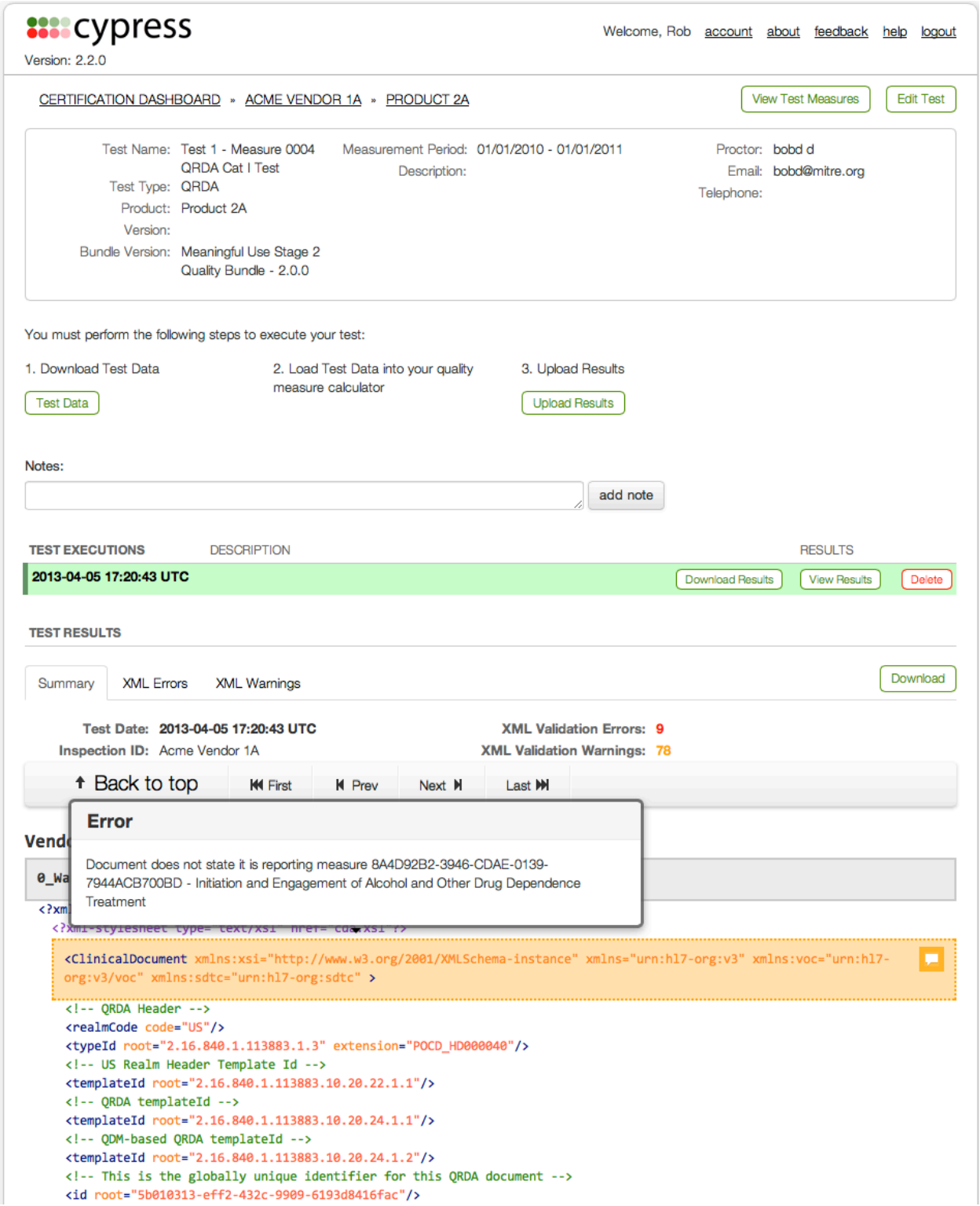
TE170.314.c – 2.2.03: The Tester downloads the Cypress test report by clicking the "Download" button at the top of the test details page, and selecting the "Report as PDF" option. The Tester should choose to save the generated PDF report in a location on their local system designated for the artifacts from this complete test (Phase 1 and Phase 2).

TE170.314.c – 2.3.04: 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 – 1.3.06.
- The QRDA Category I export submitted by the Vendor in DTR170.314.c – 2.1.03
- The PDF report generated by Cypress in TE170.314.c – 2.2.03.
- 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 – 2.3.05: 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 13: Test execution with validation errors**



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.

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.

**Guidance to ATCBs on Cypress Jira Issue #218** – QRDA I Too Much Data Expected. It was determined that Cypress is expecting more “smoking gun” data than is required by the QRDA-I specification. Section 3.2.3 “How Many Data Should Be Sent?” in the QRDA-I specification states the following: “For each data element in each referenced eMeasure, smoking gun data that offers confirmatory proof, where a patient has met the criterion.” Since the criterion only requires one encounter for the measure, “confirmatory evidence” consists of just one encounter and therefore two entries are not expected. This issue will be fixed in a future release of Cypress. In the meantime, this error for more smoking gun data beyond confirmatory proof should not be a blocking item for certification.

# 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 |
| 1.4 | Updated Test Procedure to reflect consolidation in the "Capture and Export" tests with the "Import and Calculate" tests, as well as introduced a visual inspection step with the "Capture and Export" test procedure. | April 26, 2013 |
| 1.5 | Corrected error on page 5, where the 2011 edition procedure was listed, but should have been provided using the 2014 edition procedure 170.314.(c)(1) and 170.314.(c)(3). Explicitly detailed QRDA Category 1 XML testing using one QRDA Category 1 XML per patient with multiple CQMs. Corrected grammatical errors in TE170.314.c – 2.1.03 | July 11, 2013 |
| 1.6 | Provided clarification on page 7, reflecting optionality for 170.314(c)(2)(i) Import testing | September 11, 2013 |
| 1.7 | Added Guidance to ATCBs for Cypress Jira Issue #218 – QRDA I Too Much Data Expected. | November 1, 2013 |