Prepared for:

The Office of the National Coordinator for Health Information Technology



An Open Source Meaningful Use Stage 2 Clinical Quality Measure Testing and Certification Tool

V2.0 User Guide

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Target Audience

Cypress v2.0 is the rigorous and repeatable testing tool of Electronic Health Records (EHRs) and EHR modules in calculating Meaningful Use (MU) Stage 2 Clinical Quality Measures (CQMs). Cypress v2 serves as the official testing tool for the 2014 EHR Certification program supported by the Office of the National Coordinator for Health IT (ONC).

The Cypress v2.0 User Guide has been developed for use by test proctors supporting the Meaningful Use Stage 2 program to test and certify Electronic Health Record (EHR) systems at Authorized Testing Labs (ATLs). The Cypress v2.0 User Guide may also be used by EHR software engineers, quality assurance engineers, and production release engineers who wish to use Cypress in a pre-testing mode to understand how their EHR product will perform when an ATL performs an operational test with their respective EHR product.

The Cypress v2.0 User Guide provides instructions on how to use the Cypress Testing Tool Software. This Cypress v2.0 User Guide assumes you have downloaded the Cypress v2.0 open source software and discusses the requirements and steps for testing Electronic Health Record (EHR) technology for the calculation and reporting of Clinical Quality Measures (CQM).

The Cypress tool is open source and freely available for use or adoption by the health IT community including EHR vendors and testing labs. Information detailing the setup and configuration of Cypress v2.0 open source software is available via the open source project website http://projectcypress.org.

Cypress Testing Capabilities

The Cypress v2.0 software verifies three required clinical quality measure (CQM) capabilities for EHR certification. These include:

1. Capture and Export

Capture - EHR technology seeking certification must be able to electronically record all of the data identified in the specified procedure, §170.314(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."

Export- EHR technology must be able to electronically export a data file formatted in accordance with the Quality Reporting Document Architecture (QRDA) Category I standard that includes all of the data captured for each and every CQM to which EHR technology is being certified.

The basic concept for Capture and Export is shown below in Figure 1. The primary purpose of this step is the verification of the EHR technology's ability to export data in the proper QRDA Category 1 format, and with the proper Quality Data Model (QDM) data elements.

To verify this, Cypress produces static patient data for each of the CQMs that are to be tested, and exports the relevant patients. This data is then entered into the EHR. The EHR is then commanded to export the patient test data as 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 Extensible Markup Language (XML) documents) and correctness (contain only the elements required to calculate the CQMs, and no more).

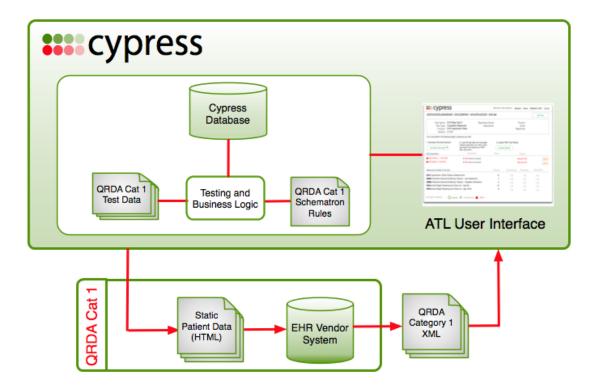


Figure 1: Capture and Export

2. Import and Calculate

Import - EHR technology must be able to electronically import a data file formatted in the QRDA Category I format.

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

3. Electronic Submission

Electronic Submission - Enables a user to electronically create a data file in QRDA Category III format for transmission of clinical quality measurement data that can be electronically accepted by Centers for Medicare & Medicaid Services (CMS).

The basic concept for Import, Calculate and Electronic Submission is shown below in Figure

- 2. The purpose of these steps, is for the automated verification that an EHR system can:
 - Import and calculate the CQM results for the quality measures being certified based on the synthetic patient data that Cypress presents to the EHR system under test.

• Generate a properly formatted summary CQM report that could be electronically submitted using QRDA Category III format.

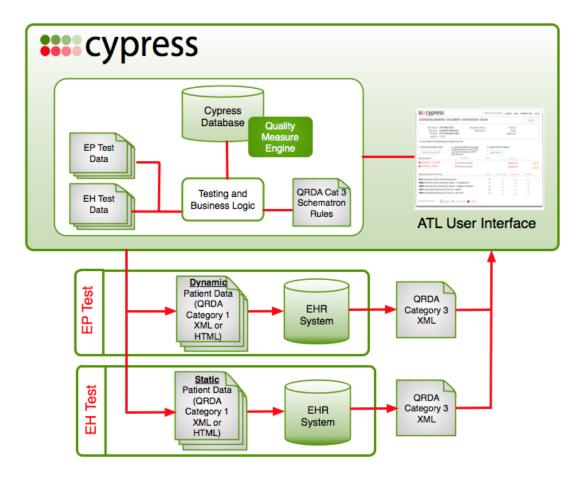


Figure 2: Import, Calculate and Electronic Submission

Testing Procedure Overview

The Figure 3 graphic below provides a general workflow of a test performed with Cypress and description of how the test procedure is organized and conducted. This test procedure is based on the ONC approved and the National Institute of Standards and Technology (NIST) published procedure augmented to include Cypress as a software tool for testing the accurate calculation, submission and degree of correctness of the CQMs.

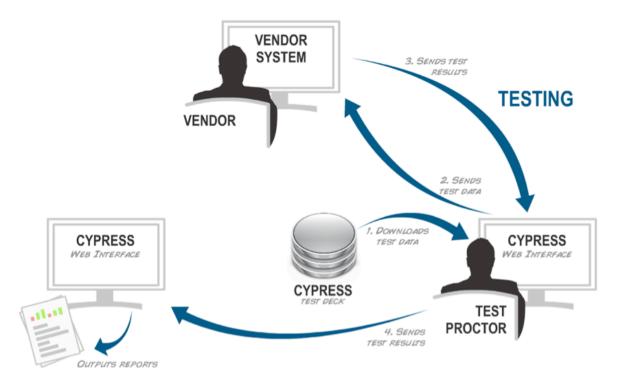


Figure 2: Authorized Testing Lab Workflow Illustration

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:

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

A complete description of the Cypress Testing Procedure can be found via the Cypress website at http://projectcypress.org/resources.html.

User Guide Detailed Description

Accessing Cypress

- To access and download the Cypress Software go to http://projectcypress.org
- There are several options and detailed instructions there for downloading and installing the Cypress software. This document is not meant to provide instructions for downloading the Cypress software, so if you need to install the software, please follow the Cypress Download Instructions.

Once you have downloaded and installed the Cypress Software, you should be able to access Cypress system via a URL, bookmark or icon you have created.

• Once you access your installed instance of Cypress, enter your Email and Password and choose **Create a new account.**

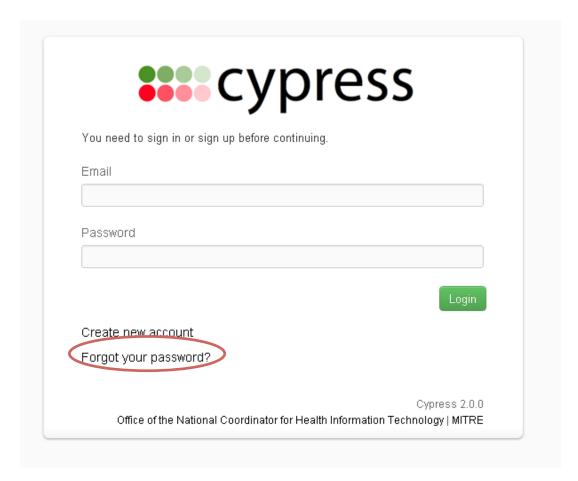


Figure 4: Cypress Login in

- If you have previously set up an account, enter your email and password and select Login.
- If you have previously created an account and forgotten your password, enter your email and select 'Forgot your Password?' And you will be sent a link to reset your password.
- Create New Account will bring you to the Account Creation and Terms and Conditions

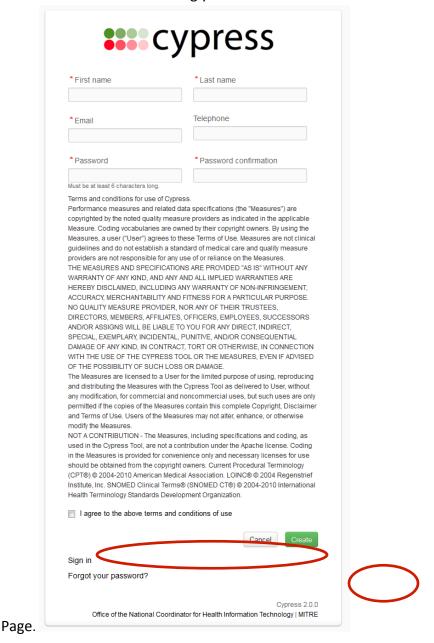


Figure 5: Cypress Account and Terms and Conditions

- To create an account, enter your First and Last Name, Email, Telephone and enter a Password and confirm your Password
- Read the Terms and conditions and check 'Agree' and select "Create' to create your Cypress Account

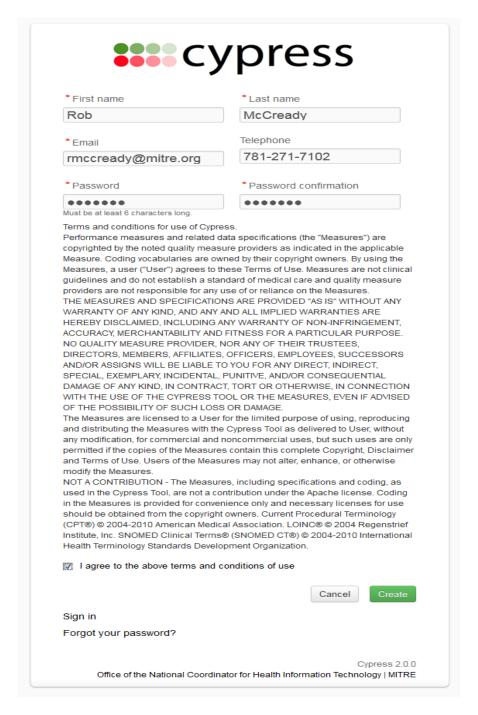


Figure 6: Cypress Account Creation

Cypress Administrative Functions

 The first page displayed after your account is created is the Certification Dashboard and the following message is displayed:

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.

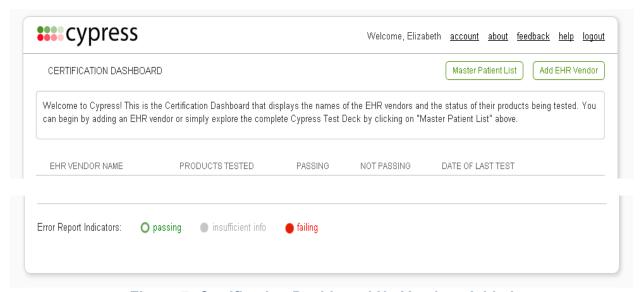


Figure 7: Certification Dashboard No Vendors Added

- There are five Cypress Administrative Functions found on the Certification Dashboard:
 - Account- Update a Cypress Account Password
 - About- Learn more about Cypress and review FAQs
 - 3. Feedback- Provide Feedback to the Cypress Team
 - 4. Help- Locate a Help email address, Copy of this User Guide and other resources
 - 5. Logout- Log out of the Cypress Application
 - 6. Master Patient List

1. Account – If you have previously set up an account, this page will allow you to change your Password

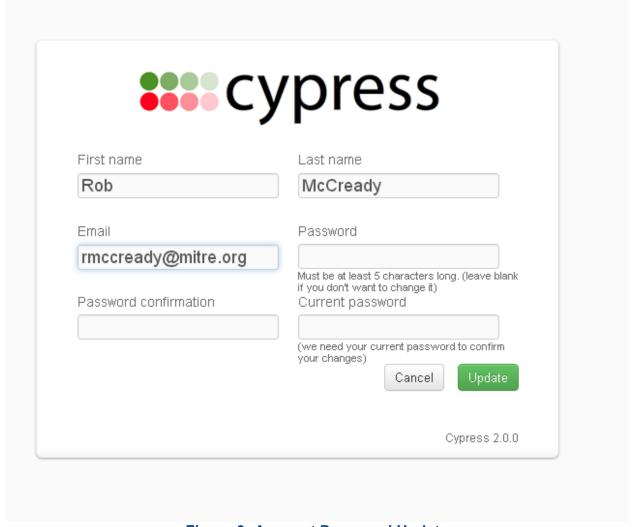


Figure 8: Account Password Update

- 2. About Learn more about Cypress via the publicly available project website
- 3. Feedback Provides several mechanisms for providing feedback on Cypress

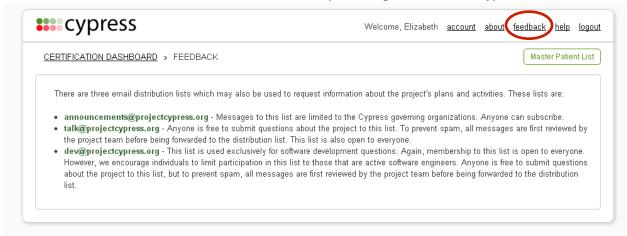


Figure 9: Cypress Feedback Mechanisms

- **4.** Help Provides help contact and additional reference information via the Cypress v2.0 Frequently Asked Questions (FAQ) page
- 5. Logout Allows you to logout of Cypress and return to Account Sign in

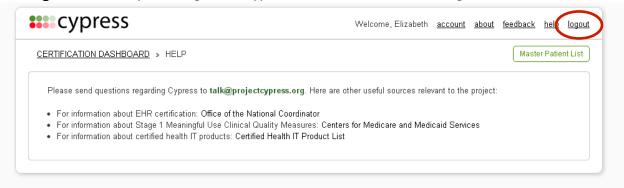


Figure 10: Cypress v2.0 Logout

- 6. Master Patient List- Provide a list of all test data for CQMs
 - · You can select and download individual or all the patient data records
 - You can select a record and Cypress v2.0 will display the patient test record applicable data requirements and CQM qualifiers

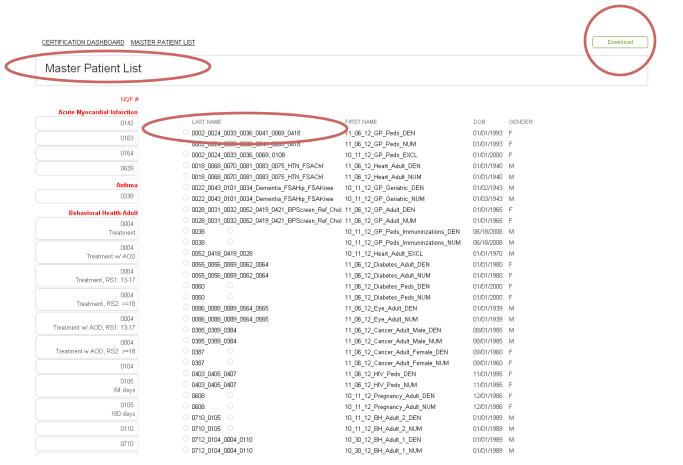


Figure 11: Master Patient List of Test Patients

- Patient test record 0002_0024_0033_0036_0041_0069_0418, 11_06_12_GP_Peds_DEN applicable data requirements and CQM qualifiers is displayed
- You can download the individual files

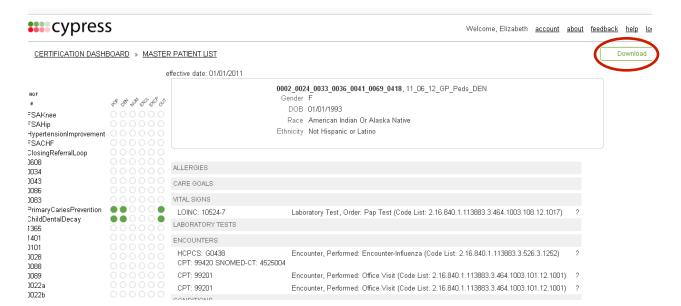


Figure 12: Patient Test Record Data Requirements and CQM Qualifiers

Patient Records are downlanded to a Zip file

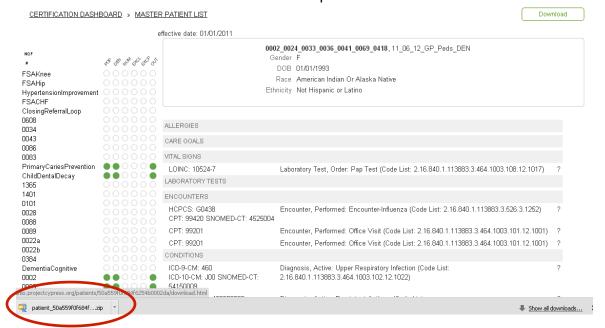


Figure 13: Downloaded Patient Data Zip File

Prepare for Cypress v2.0 Testing

- Once you have created an Account, the next step is to add a Vendor and Contact Information
- Select Add Vendor from the Certification Dashboard

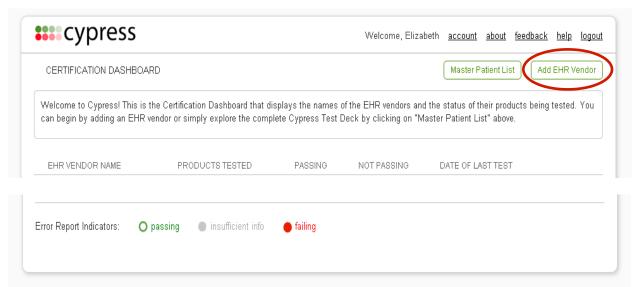


Figure 14: Certification Dashboard Select Add Vendor

- The Vendor Information and Contact Form will be displayed
- Complete the Vendor Information and Contact Form and select Create

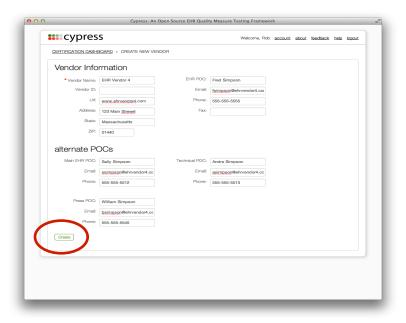


Figure 15: Vendor and Contact Form

 Once the Vendor Account is created, the Vendor name will be displayed on the Certification Dashboard

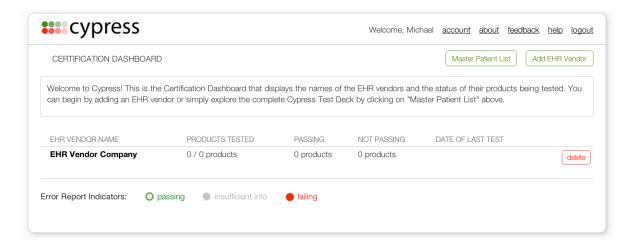


Figure 16: Vendor Certification Dashboard with no products added

- The next step is to enter Product information (Product Name, Description and Version).
 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.
- Once the Product information is entered, select Create

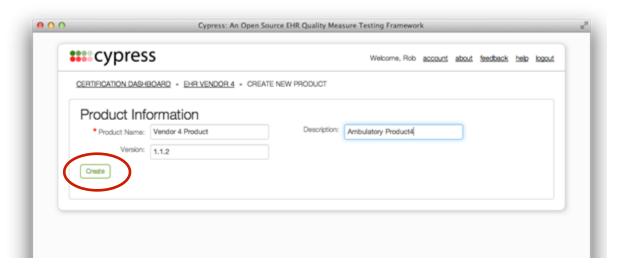


Figure 3: EHR Product form

 The Vendor, EHR Point of Contact and Product will now display on the Certification Dashboard

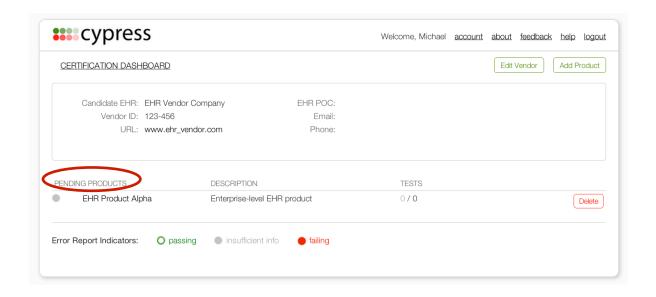


Figure 4: Certification Dashboard showing a vendor with one product added

• Select the Pending Product and Certification Dashboard with no tests will be displayed

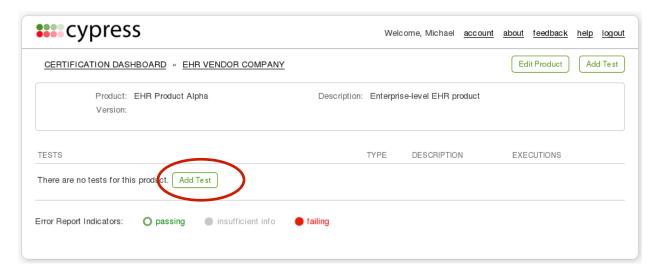


Figure 5: Dashboard showing Product and No Tests Added

- Select 'Add Test' and 'Create New Test' Page is displayed
- Add a Test Name, Brief Description and choose Test Type (EP, EH, QRDA1)

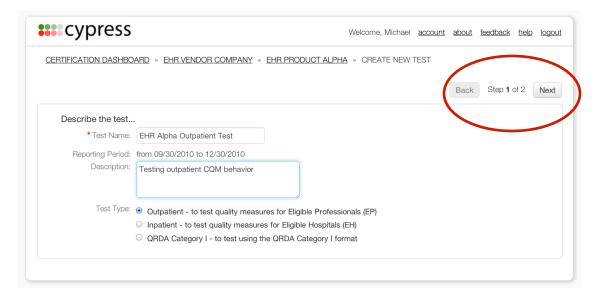


Figure 20: Create New Test - Step 1 Basic Information

 Specify the measures that will be tested, the format and the method to use for loading the test patients

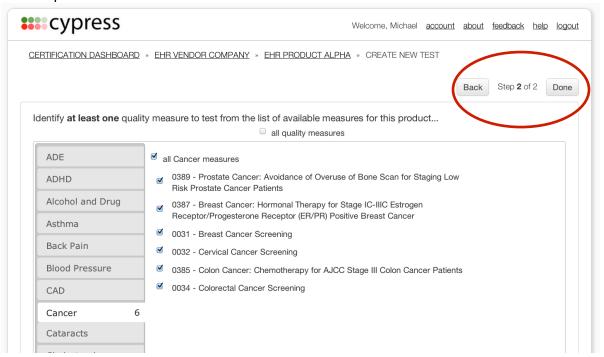


Figure 21: Create New Test - Step 2 CQM selection

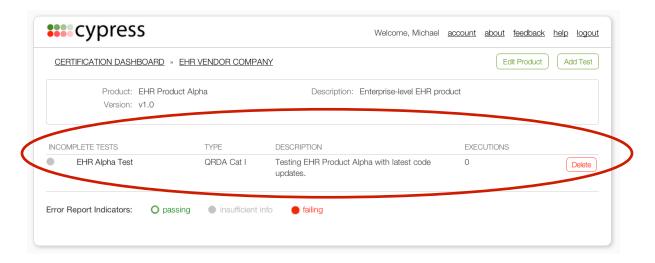


Figure 22: New Test Created

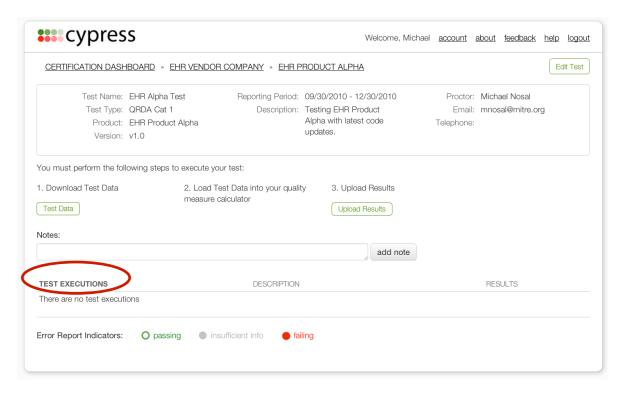


Figure 23: Dashboard with no Test Executions

Test Execution

- This process evaluates the capability of the EHR system under test (SUT) to electronically generate the proper CQM artifacts for the CQMs being certified.
- The Test Proctor provides the Cypress v2.0 Test Data for the clinical quality measures for which the EHR system will be tested in the format selected to the EHR vendor via the Download Test Data.
- Depending on the test, the Vendor manually inputs or electronically downloads the patient test data into their EHR system.
 - Capture and Export: manual test data input (using html)
 - o Import and Calculate: QRDA Category 1 electronic input
- The Test Proctor examines the CQMs implemented in the EHR.

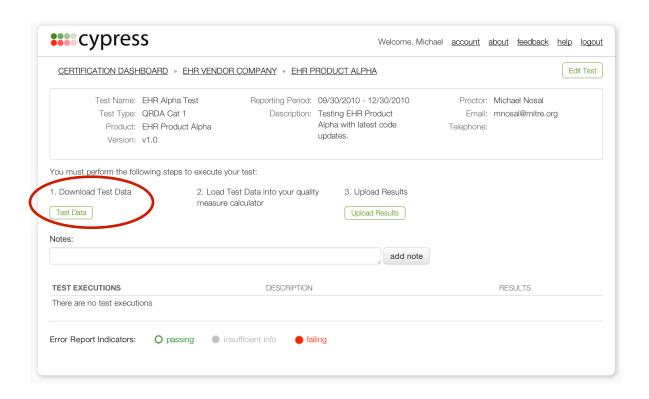


Figure 24: Download Patient Data for Import

A list of the patient records required for testing the selected CQMs is downloaded

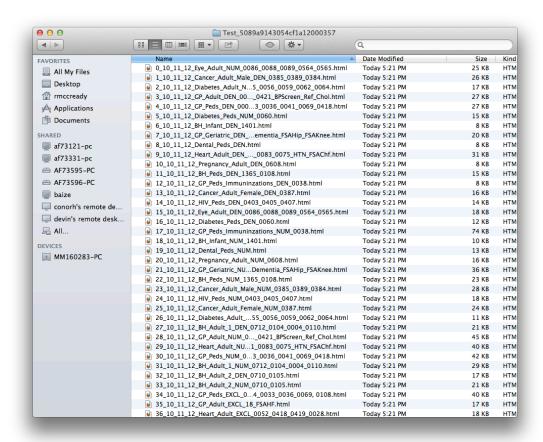


Figure 25: Listing of Zip file HTML Patient Test Data for selected CQMs to be tested

Select a single patient record and open the html

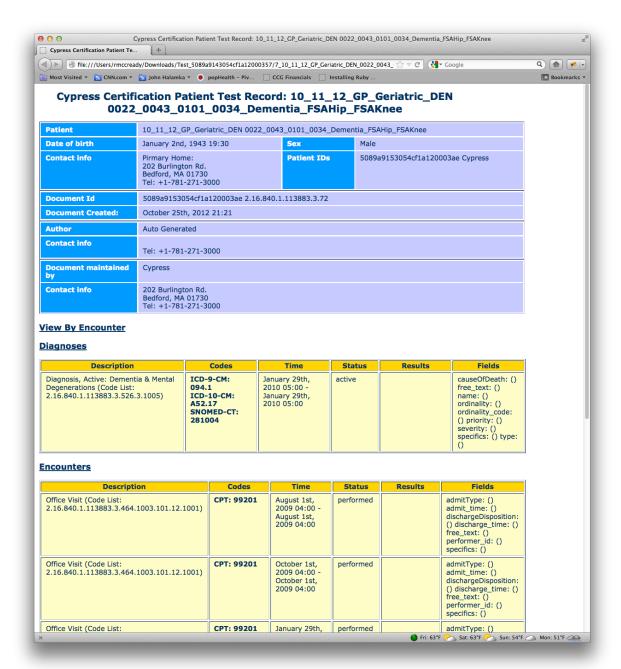


Figure 26: HTML for one Patient Record

 Calculated Test Results in the QRDA Category III format are uploaded from the Certification Dashboard

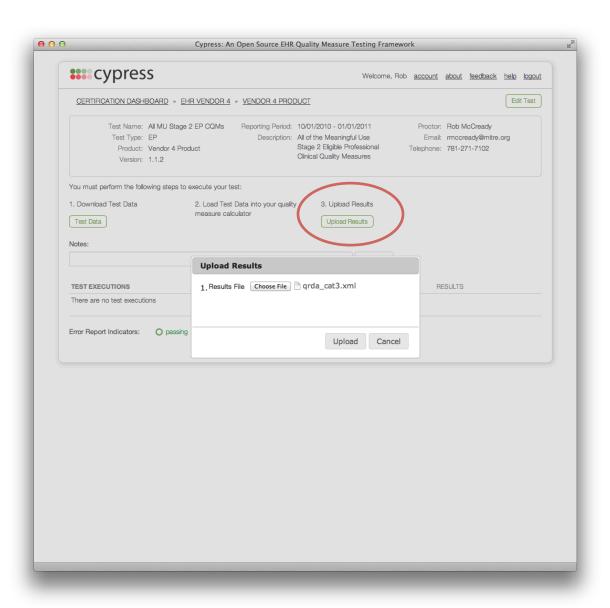


Figure 6: Upload test execution results

• The Test Proctor validates that the proper CQM artifacts in QRDA Category III file format for the test being performed are electronically generated by the EHR SUT.

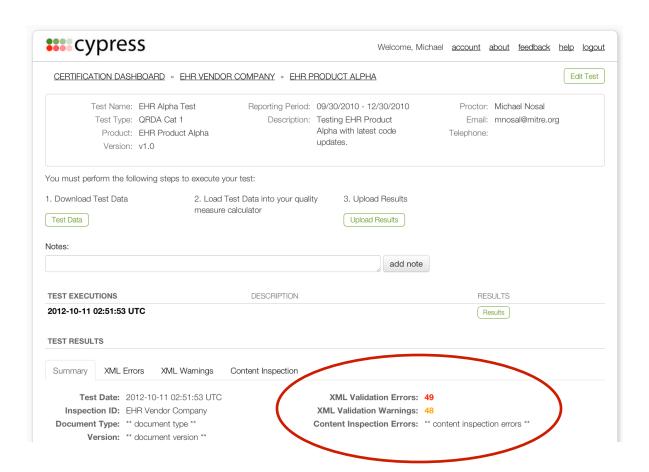


Figure 7: Test execution with validation errors

Further detail of the validations errors available and noted in Figure 31

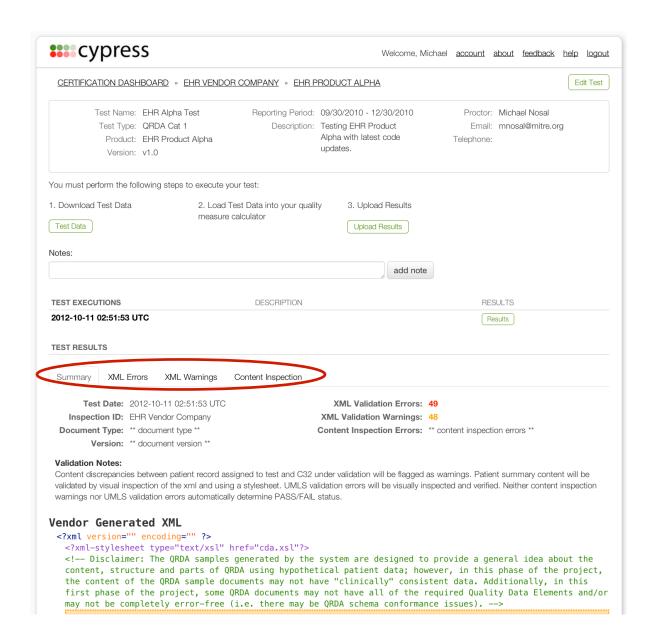


Figure 8: Details of test execution with errors

Further Testing can occur until all CQMs pass the validation test

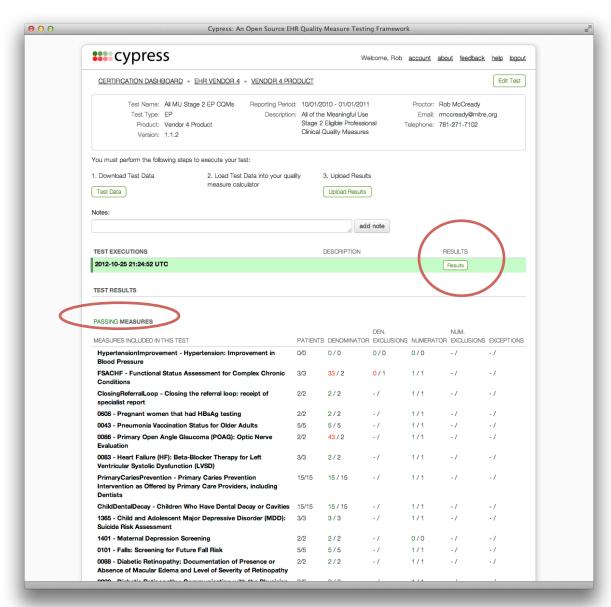


Figure 90: Test execution with no errors calculated results against expected results

Test Execution Notes

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 v2.0 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 v2.0 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 v2.0 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 Test Proctor 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.

Submit

Electronically submit generated CQM artifacts

Evaluates the capability 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 Test Proctor 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 Test Proctor 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 Test Proctor 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 v2.0 User Interface and the Cypress-supplied XML Schema validation.
- The Test Proctor 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 v2.0 User Interface and the Cypresssupplied 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 Test Proctor validates the submission of the QRDA Category III, the Test
 Proctor evaluates and displays the accuracy of the submitted clinical quality measure
 results via the Cypress v2.0 User Interface.
- The Test Proctor 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 Test Proctor deems relevant into a single
 archive file that is cryptographically signed.

Acronyms

ATL Authorized Testing Lab

CMS Centers for Medicare & Medicaid Services

CQM Clinical Quality Measure

EH Eligible Hospital

EHR Electronic Health Record

EP Eligible Professional

HTML Hypertext Markup Language

NIST National Institute of Standards and Technology

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