REAL WORLD TESTING PLAN TEMPLATE

BACKGROUND & INSTRUCTIONS

Under the ONC Health IT Certification Program (**Certification Program**), health IT developers are required to conduct Real World Testing of their certified health IT (45 CFR 170.405). The Office of the National Coordinator for Health Information Technology (ONC) issues Real World Testing resources to clarify health IT developers' responsibilities for conducting Real World Testing, to identify topics and specific elements of Real World Testing that ONC considers a priority, and to assist health IT developers in developing their Real World Testing plans. Health IT developers have maximum flexibility to develop innovative plans and measures for Real World Testing. As developers are planning how they will execute Real World Testing, they should consider the overall complexity of the workflows and use cases within the care settings in which they market their certified health IT to determine the approaches they will take. This Real World Testing plan template was created to assist health IT developers in organizing the required information that must be submitted for each element in their Real World Testing plan. While the use of this template is voluntary, health IT developers may find it useful in preparing their Real World Testing plans. Health IT developers must submit one plan for each year of Real World Testing (see resources listed below for specific timelines and due dates). ONC does not encourage updating plans outside the submission timeline and will not post updates on the Certified Health IT Product List (CHPL). If adjustments to approaches are made throughout Real World Testing, the health IT developer should reflect these adjustments in their Real World Testing results report. ONC expects that the Real World Testing results report will include a description of these types of changes, the reasons for them, and how intended outcomes were more efficiently met as a result. **While every effort has been made to ensure the accuracy of restatements of 45 CFR Part 170, this template is not a legal document. The official program requirements are contained in the relevant laws and regulations. This resource should be read and understood in conjunction with the following companion resources, which describe in detail many of the Program requirements referenced in this resource.**

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

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

- 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program final rule, 85 FR 25642 (May 1, 2020) (**ONC Cures Act Final Rule**)
    - Section VII.B.5 — "Real World Testing"
- Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Final Rule, 89 FR 1192 (March 11, 2024) (**HTI-1 Final Rule**)
    - Section III.E — "Real World Testing"

GENERAL INFORMATION

- **Plan Report ID Number**: [For ONC-Authorized Certification Body use only]
- **Developer Name**: Eyefinity, Inc
- **Product Name(s)**: Eyefinity EHR
- **Version Number(s)**: 7
- **Certified Health IT Product List (CHPL) ID(s)**: 15.04.04.2900.Eyef.07.17.1.221219
- **Developer Real World Testing Plan Page URL**: https://www.eyefinity.com/real-world-testing.html

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STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) STANDARDS UPDATES

Voluntary standards updates must be addressed in the Real World Testing plan. Real World Testing plans must include all certified health IT updated to newer versions of standards prior to August 31 of the year in which the updates were made.

Standard (and version)	**Not Applicable**
Updated certification criteria and associated product	
Health IT Module CHPL ID	
Date of ONC ACB notification	
Date of customer notification	
Conformance method and measurement/metric(s)	

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

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

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

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

- Adoption Rate
- Summative Testing
- Interactive Testing

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

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

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

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MEASUREMENT(S)/METRIC(S) USED IN OVERALL APPROACH

Adoption Rate

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

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

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

Measurement/Metric	Description
Certified capabilities that are licensed separately	Identify which certified capabilities are licensed separately from the base EHR license. *Examples may include eRx, CQMs, public health, etc.*
Number of installs/users who licensed a certified capability	Where applicable, identify the number of licensed installs/users of a given certified capability.
Number of installs/users that have used the certified capability in the preceding 365 days	Where applicable, identify the number of active installs/users of a given certified capability.

Care Settings for Measurement/Metric(s)

Care Setting	Justification
Dermatology	Dermatologists comprise a relatively large proportion of our EMA business.
Ophthalmologists	Ophthalmologists comprise a relatively large proportion of our EMA business.
Orthopedics	Orthopedists comprise a relatively large proportion of our EMA business.
Other specialties	Otolaryngology, Pain Management, Podiatry, Urology, and OBGYN each comprise a relatively smaller proportion of our EMA business.
Plastics Surgery	Plastic surgery providers frequently operate as a cash business and generally do not participate in incentive programs.

SUMMATIVE TESTING

The following metrics will be measured by viewing audit logs and reporting systems available to track the behavior of the certified Health IT module during a given time frame. All metrics are designed to reflect the core elements of the criteria, demonstrate interoperability, and demonstrate the success rate of the certified capability being used.

In most cases we elected to record these metrics over a minimum 90-day period to reflect the reporting periods typically required for compliance with the federal incentive programs.

The continued measurable use of certified capabilities will provide implicit evidence of successful implementation of the required certified capability. This is especially meaningful in cases where interoperability with outside systems is demonstrated. In cases where it is not possible to determine “success” via an explicit confirmation by a receiving system, success will be defined as a transmission was made where no error was received from the destination system or its intermediaries.

Additionally, we will review internal customer and vendor issue tracking systems for reports of failures or unsatisfactory performance in the field.

Criteria covered in this Real-World Test plan:

- §170.315(b)(1) – Transitions of Care
- §170.315(b)(2) – Clinical Information Reconciliation and Incorporation
- §170.315(b)(3) – Electronic Prescribing
- §170.315(b)(10) – Electronic Health Information Export
- §170.315(c)(1) – Clinical Quality Measures
- §170.315(e)(1) – View, Download, and Transmit to 3rd Party

- §170.315(f)(5) – Transmission to Public Health Agencies – Electronic case reporting
- §170.315(g)(7) – Application Access – Patient Selection
- §170.315(g)(9) – Application Access – All Data Request
- §170.315(g)(10) – Standardized API for patient and population services
- §170.315(h)(1) – Direct Project

Certification Criteria	Relied Upon Software *(if applicable)*	Metric Description
§ 170.315 (b)(1) Transitions of care	Updox	**Over a 90 day period**: 1. Number of CCDAs created 2. Number of CCDAs sent via edge protocols 3. Number of CCDAs received via edge protocols
§ 170.315 (b)(2) Clinical information reconciliation & incorporation		**Over a 90 day period**: 1. Number of CCDA received 2. Number of CCDA received and patient matched 3. Number of CCDA received and reconciled
§ 170.315 (b)(3) Electronic prescribing	Surescripts eRx	**Over a 90 day period**: 1. Number of prescriptions created 2. Number of prescriptions changed 3. Number of prescriptions canceled 4. Number of prescriptions renewed
§ 170.315 (b)(10) Electronic Health Information export		**Over a 90 day period**: 1. **Single Patient Export**: Number of EHI Export requests processed and delivered for a single patient's data export 2. **Patient Population Export**: Number of requests processed and delivered for a patient population's EHI data
§ 170.315 (e)(1) View, download, and transmit to 3rd party	Updox	**Over a 90 day period**: 1. Number of views of health information by a patient or authorized representative 2. Number of downloads of health information by a patient or authorized representative 3. Number of transmissions of health information by a patient or authorized representative using unencrypted email 4. Number of transmissions of health information by a patient or authorized representative using encrypted method
§ 170.315 (f)(5) Transmission to public health agencies - electronic case reporting	Updox, eCRNow application	**Over a 90-day period:** ● Number of eICRs generated and transmitted to Public Health Authorities (PHAs) via eCR Now, for reportable conditions. ● Number of Reportability Responses received for eICRs submitted.

§ 170.315 (g)(10) Standardized API for patient & population services		**Over a 90-day period:** 1. API Requests Served - using a valid patient ID or token: a. **Numerator**: # of successful responses b. **Denominator:** Total requests of certified API(s) 2. API Users with at least one successful response – Validates successful API use spanning current API Users: a. **Numerator**: Total API Users with at least one successful response b. **Denominator:** Total API Users with at least one request 3. 3rd party Personal Health Record (PHR) Apps with at least one successful response – Validates successful API use spanning current Synapsis-based apps: a. **Numerator:** Total number of Apps with at least one successful response b. **Denominator**: Total number of Apps with at least one request.
§ 170.315 (h)(1) Direct Project	Updox	**Over a 90 day period**: 1. Number of Direct Messages sent 2. Number of Delivery Notifications received 3. Number of Direct Messages received

Justification & Expected Outcomes for Summative Testing Metrics

Certification Criteria	Justification & Methodology	Expected Outcome
§ 170.315 (b)(1) Transitions of care	This criterion requires the ability of a certified Health IT module to create CCDAs according to specified standards and vocabulary code sets, as well as send and receive CCDAs via edge protocols. We intend to demonstrate the required certified capabilities by demonstrating how often CCDAs are created and exchanged with other systems to demonstrate the certified capability is available and effective, regardless of the frequency it is used.	Our expectation is there will be moderate utilization by providers with a high success rate. Success is defined as CCDAs being created and sent via Direct with expected errors.

§ 170.315 (b)(2) Clinical information reconciliation and incorporation	This criterion requires the ability of a certified Health IT module to take a CCDA received via an outside system and match it to the correct patient; reconcile the medication, allergy, and problem lists; and then incorporate the lists into the patient record. While this certified capability is available to our users, most providers in the real world typically prefer to perform these steps manually and elect to save any outside received CCDAs as attachments to the patient record. Therefore, we intend to record the frequency that providers are electronically reconciling and incorporating CCDAs that were received from outside providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used.	Our expectation is there will be low utilization by providers with a high success rate.
§ 170.315 (b)(3) Electronic prescribing	This criterion requires the ability of a certified Health IT module to perform prescription-related electronic transactions (eRx) using required standards. It is not possible to demonstrate the correct standards were used because it is not feasible to obtain copies of eRx documents from “outside” companies or pharmacies who have no incentive to participate. Therefore, we intend to demonstrate the required certified capabilities are effective by demonstrating how often eRx transactions are performed by examining reports from our eRx partner (Surescripts). This will demonstrate that not only are the eRx transactions sent from the certified Health IT module, but that the transactions are successfully received by the eRx clearinghouse.	Our expectation is there will be high utilization by providers with a high success rate.
§ 170.315 (b)(10) Electronic Health Information export	This criterion requires the ability of a certified Health IT module to enable a full export of EHI data for a single patient and/or a patient population. This measure will demonstrate authorized user’s ability to generate a single patient EHI export from within EMA and also illustrate our ability to process and deliver multi-patient EHI Export requests by providing a count of requests processed from our production environment over a 90-day period.	Our expectation is there will be moderate utilization by providers with a high success rate.

§ 170.315 (c)(1) Clinical Quality Measures (CQMs)	C1 requires a certified Health IT module to record required data, calculate CQMs from the recorded data, and export the data in QRDA Category 1 format, however the specialties that Modernizing Medicine serves do not qualify for most of the CMS incentive programs requiring the use of eCQMs. EMA supports only one eCQM (CMS68 Documentation of Current Medications in the Medical Record) EMA has its own qualified MIPS registry called the Modernizing Medicine Registry that reports MIPS CQMs. EMA also partners with other qualified registries that are meaningful to EMA customer practices, but those also do not make use of the c1 certified capability. We intend to record the frequency that CQM files are imported and/or exported by providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used.	Our expectation is there will be moderate utilization by providers with a high success rate.
§ 170.315 (e)(1) View, download, and transmit to 3rd party	This criterion requires the ability of a certified Health IT module to provide patients access to a patient portal with the ability to view, download, and send their health care records to other providers via encrypted or unencrypted transmission methods in CCDA format. We intend to record the frequency that patients are viewing, downloading, and transmitting their records from the portal using the certified capabilities to demonstrate the certified capability is available and effective, regardless of the frequency it is used.	Our expectation is there will be moderate utilization by patients for view and lower utilization for download and transmit with a high success rate for all certified capabilities.
§ 170.315 (f)(5) Transmission to public health agencies-electronic case reporting	This measure will evaluate our ability to send electronic case reports to public health agencies through the AIMS Platform and receive Reportability Responses for eICRs sent.	We do not expect significant adoption by clients as the enforcement date is Dec 2025. Our expectation is there will be low to moderate utilization by providers with a high success rate.
§ 170.315 (g)(10) Standardized API for patient and population services	This criterion requires the certified Health IT module to provide a FHIR Server API and supporting documentation that enable external applications to request patient data by category from the certified Health IT FHIR Server.	Our expectation is there will be low utilization by providers with a high success rate.

§ 170.315 (h)(1) Direct Project	This criterion requires the ability of a certified Health IT module to record the frequency that direct messages are sent and received by providers, along with how often MDNs are sent and received. Since not all systems respond with MDNs, we cannot reliably use that metric to define success. Furthermore, it is not feasible to obtain copies of Direct Messages from "outside" developers or providers who have no incentive to participate in this exercise. Therefore, we intend to demonstrate the required certified capabilities by demonstrating how often Direct Messages are exchanged with other systems to demonstrate the certified capability is available and effective, regardless of the frequency it is used.	Our expectation is there will be moderate utilization by providers with a high success rate.

INTERACTIVE TESTING

The following test plans will be executed to demonstrate Real World certified capabilities for criteria where metrics are not available, because there is 0 adoption to date of the criteria.

EMA will conduct interactive testing for the following criteria:

- § 170.315(c)(1) Clinical quality measures (CQMs)
- § 170.315(g)(7) Application access—Patient Selection
- § 170.315(g)(9) Application access—all data request

Interactive Testing Metrics

Certification Criteria	Relied Upon Software *(if applicable)*	Description
§ 170.315 (c)(1) Clinical Quality Measures (CQMs)		**Methodology:** Modernizing Medicine will partner with two providers from different specialties and use test patients in the providers' Real-World production system to enter test patients that qualify for the eCQM measure and export their QRDA file. Modernizing Medicine will enter test data sufficient to fulfill the reporting for CMS68 CMS Documentation of Current Medications in the Medical Record.

§ 170.315 (g)(7) Application access - patient selection **§ 170.315 (g)(9)** Application access - all data request		**Methodology:** Modernizing Medicine will partner with 1 customer, to enter test patients into their production environment and then use the dashboard UI to verify their identity and query for their token for subsequent queries. The patient will follow these high-level steps: ● Test user logs into the test app as a patient and looks up their test results. ● Test app queries the API for discrete CCDS fields ● Test app queries the API for patient CCDA documents

Justification & Expected Outcomes for Interactive Testing Metrics

Certification Criteria	Justification	Expected Outcome
§ 170.315 (c)(1) Clinical Quality Measures (CQMs)	The specialties which Modernizing Medicine serves do not qualify for most of the CMS incentive programs requiring the use of eCQMs. EMA currently supports only one eCQM (CMS68 Documentation of Current Medications in the Medical Record) EMA has its own qualified MIPS registry called the Modernizing Medicine Registry that reports MIPS CQMs. EMA also partners with other qualified registries that are meaningful to EMA customer practices, but those also do not make use of the c1 certified capability.	These certified capabilities are available in the production environment, however the likelihood that EMA customer base will use them is very low unless CMS were to introduce new eCQMs that are more meaningful to our clinical focus. Visual inspection will confirm that the data required to record the certified CQM can be denoted within the patient record.
§ 170.315 (g)(7) Application access - patient selection **§ 170.315 (g)(9)** Application access - all data request	These criteria will be tested together. Modernizing Medicine anticipates that as RESTful standards mature & consolidate, we will see more adoption of the API certified capability in the Real World, but to date there have not been any app developers who have built applications for our specialized customer base.	Low to moderate usage as adoption of alternate means, (g)(10) FHIR APIs and (b)(10) EHI Export, grows.

SCHEDULE OF KEY MILESTONES

Real World test planning will commence in the first quarter of 2025. Each phase is expected to take 90-days to complete, with report writing to occur at the end of 2025/early 2026.

Key Milestone	Care Setting	Date/Time frame
Scheduling & logistics	• Dermatology • Ophthalmology/Optometry • Orthopedics • Other specialties • Plastics	90 days
Data collection	• Dermatology • Ophthalmology/Optometry • Orthopedics • Other specialties • Plastics	90 days
Review & collate data	• Dermatology • Ophthalmology/Optometry • Orthopedics • Other specialties • Plastics	90 days
Writing Report	• Dermatology • Ophthalmology/Optometry • Orthopedics • Other specialties • Plastics	90 days

ATTESTATION

The Real World Testing plan must include the following attestation signed by the health IT developer authorized representative.

Note: The plan must be approved by a health IT developer authorized representative capable of binding the health IT developer for execution of the plan and include the representative's contact information.ii

This Real World Testing plan is complete with all required elements, including measures that address all certification criteria and care settings. All information in this plan is up to date and fully addresses the health IT developer's Real World Testing requirements.

Authorized Representative Name: Robert Winchell

Authorized Representative Email: rob.winchell@eyefinity.com

Authorized Representative Phone: 916.858.5746

Authorized Representative Signature

October 29, 2024

Date

Certified health IT continues to be compliant with the certification criteria, including the required technical standards and vocabulary codes sets; certified health IT is exchanging EHI in the care and practice settings for which it is marketed for use; and EHI is received by and used in the certified health IT. (85 FR 25766)

[ii] https://www.federalregister.gov/d/2020-07419/p-3582