MaximEyes.com v1.1

Real World Testing Plan

General Information

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

Developer Name: First Insight Corporation

Product Name(s): MaximEyes.com

Version Number(s): 1.1

Certified Health IT: §170.315(b)(1), §170.315(b)(2), §170.315(c)(1), §170.315(c)(2), §170.315(c)(3), §170.315(f)(5), §170.315(f)(7), §170.315(g)(7), §170.315(g)(8), §170.315(g)(9), § 170.315(g)(10)

Product List (CHPL) ID(s): 15.04.04.2729.Maxi.01.00.1.201014

Developer Real World Testing Page URL: https://www.first-insight.com/resources/certifications/

Justification for Real Word Testing Approach

Provide an explanation for the overall approach to Real World Testing, including an outline of the approach and how data will be used to demonstrate successful Real World Testing[1].

All measures should reasonably align with the elements within a Real World Testing plan, the scope of the certification, the types of settings in which the certified health IT is marketed, and other factors relevant to the implementation of the certified Health IT Module(s). The justification should reflect how each element within the plan is relevant to the developer's overall strategy for meeting the Real World Testing Condition and Maintenance of Certification requirements.

Note: A single Real World Testing plan may address multiple products and certification criteria for multiple care settings.

MaximEyes.com database queries will be reviewed to determine the frequency of transport for several workflows used by Optometrists and Ophthalmologists to perform interoperability. The metrics collected will allow us to ensure that our product is conforming to interoperability criteria within the real world use cases performed by our users.

[1] 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)

Standards Updates (including Standards Version Advancement Process (SVAP) and United States Core Data for Interoperability (USCDI))

Both required and 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.

Describe approach(es) for demonstrating conformance to all certification requirements using each standard to which the health IT is certified. List each version of a given standard separately. For each version of a standard submit the following:

- ✓ *Identify standard versions*
- ✓ *Indicate what certification criteria in which product(s) has been updated*
- ✓ *If reporting for multiple products, identify the certification criteria that were affected by the update for each of the associated products*
- ✓ *CHPL ID for each Health IT Module*
- ✓ *Method used for standard update (e.g., SVAP)*
- ✓ *Date notification sent to ONC-ACB*
- ✓ *If SVAP, date notification sent to customers*
- ✓ *Measure used to demonstrate conformance with updated standard(s)*
- ✓ *Which certification criteria were updated to USCDI and/or to which version of USCDI was the certification criteria updated?*

Standard (and version)	All standard versions are those specified in USCDI v1. We plan to use SVAP to update the (c)(3) module to support the new version of the CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2023 during the testing period.
Updated certification criteria and associated product	§170.315(c)(3) – Clinical quality measures (CQMs) — report MaximEyes.com v1.1
Health IT Module CHPL ID	15.04.04.2729.Maxi.01.00.1.201014
Method used for standard update	SVAP
Date of ONC-ACB notification	June/July 2024
Date of customer notification (SVAP only)	June/July 2024
Conformance measure	§170.315(c)(3) – Clinical quality measures (CQMs) — report
USCDI-updated certification criteria (and USCDI version)	The plan documents the support of all USCDI v1 data elements.

Measures Used in Overall Approach

Each plan must include at least one measurement/metric that addresses each applicable certification criterion in the Health IT Module's scope of certification. Describe the method for measuring how the approach(es) chosen to meet the intent and purpose of Real World Testing.

For each measurement/metric, describe the elements below:

- ✓ Description of the measurement/metric

- ✓ Associated certification criteria
- ✓ Justification for selected measurement/metric
- ✓ Care setting(s) that is addressed
- ✓ Expected outcomes

Description of Measurement/Metric

Describe the measure(s) that will be used to support the overall approach to Real World Testing.

Measurement/Metric	Description
# of CCDA files sent by the provider via secure email to an external physician, # of CCDAs imported by the physician # of CCDA files reconciled # of CCDA files uploaded to the patient portal.	In situations where documentation needs to be coordinated between providers and patients both within and outside of a healthcare organization. The shared documentation includes transitions of care documents, healthcare plan documents, health information provided to the patient through a portal, and the export of patient healthcare records .The transitions of care documents are shared between organizations using Edge protocol technology (Direct, SMTP email) and with the patient through a portal with the ability to view, download, and transmit. Additionally, the patient health information can be shared with external organizations using an export function.
# of times QRDA I files were exported, # of times QRDA III file was exported, # of times QRDA I file was imported.	Provider is able to import CQM measures via QRDA category I and calculate combined system data with imported data. QRDA category III can be exported with only system data or combined imported and system data and use to report to incentive programs.
# of times health care surveys were exported, # of patients the health care surveys were exported for # of eCR files exported, # of patients the eCR was exported for.	Providers are able to generate data through clinical processes involving patient care and are able export and electronically submit the data.
#of patients searched, # of times the encounter element was fetched and the data that was fetched, # of CCDAs generated.	Developer will test the ability of its certified API technology to manage multiple applications' requests for patient data using the single patient services requirements at §170.315(g)(7), §170.315 (g)(8), §170.315(g)(9).
#of apps approved by MaximEyes.com #of apps registered on the developer portal #of patient apps who had accessed the patient data via the APIs.	The developer will test the ability of its certified API technology to manage multiple applications' requests for patient data using the single patient and bulk patient service requirements at §170.315(g)(10).

Measurement/Metric	Description
#of provider apps who had accessed the patient data via the APIs #of system apps who had accessed the patient data via the APIs # of patients who had accessed their data via the APIs.	

Associated Certification Criteria

List certification criteria associated with the measure and if updated to the 2015 Edition Cures Update criteria.

Measurement/Metric	Associated Certification Criteria
# of CCDA files sent by the provider via secure email to an external physician, # of CCDAs imported by the physician # of CCDA files reconciled # of CCDA files uploaded to the patient portal.	§170.315(b)(1) Transitions of care §170.315 (b)(2): Clinical Information Reconciliation and Incorporation
# of times QRDA I files were exported, # of times QRDA III file was exported, # of times QRDA I file was imported.	§170.315(c)(1) - Clinical quality measures (CQMs) — record and export §170.315(c)(2) - Clinical quality measures (CQMs) — import and calculate §170.315(c)(3) - Clinical quality measures (CQMs) — report
# of times health care surveys were exported, # of patients the health care surveys were exported for # of eCR files exported, # of patients the eCR was exported for.	§170.315(f)(5) - Transmission to public health agencies — electronic case reporting §170.315(f)(7) - Transmission to public health agencies — health care surveys
#of patients searched, # of times the encounter element was fetched and the data that was fetched, # of CCDAs generated.	§170.315(g)(7) - Application access — patient selection §170.315(g)(8) - Application access — data category request §170.315(g)(9) - Application access — all data request
#of apps approved by MaximEyes.com #of apps registered on the developer portal	§ 170.315(g)(10) - Standardized API for patient and population services

Measurement/Metric	Associated Certification Criteria
#of patient apps who had accessed the patient data via the APIs #of provider apps who had accessed the patient data via the APIs #of system apps who had accessed the patient data via the APIs # of patients who had accessed their data via the APIs.	

Justification for Selected Measurement/Metric

Provide an explanation for the measurement/metric selected to conduct Real World Testing.

Measurement/Metric	Justification
# of CCDA files sent by the provider via secure email to an external physician, # of CCDAs imported by the physician # of CCDA files reconciled # of CCDA files uploaded to the patient portal.	This use case will demonstrate the provider to provider communication and provider to patient communication.MaximEyes.com includes two functionalities of interest: (A) Send transition of care/referral summaries and (B) Receive transition of care referral summaries, including (C) XDM processing. Transitions of care documents are shared using Edge protocols (e.g., SMTP, Direct) while other EHI may be shared through the patient portal using downloads and encrypted or unencrypted transmissions. This metric will provide information on the number of files sent /received and reconciled.
# of times QRDA I files were exported, # of times QRDA III file was exported, # of times QRDA I file was imported.	MaximEyes.com users participating in the regulatory programs should successfully be able to submit the quality measures for all the patients or the filtered requests for the given reporting period. This will provide a metric on the use of QRDA category III usage.
# of times health care surveys were exported, # of patients the health care surveys were exported for # of eCR files exported, # of patients the eCR was exported for.	MaximEyes.com supports exporting of data for health surveys and electronic case reporting for electronic transmission to public health agencies. The goal of this approach is to demonstrate that both the export and conformance capabilities of health care surveys and case reports are consistent with the requirements of certification criterion.
#of patients searched, # of times the encounter element was fetched and the data that was fetched, # of CCDAs generated.	Since the application provides access to specific patient data through the FHIR® interfaces, this will provide a metric on the use of FHIR® APIs to access patient data. Additionally, credentialing requirements will be tested indirectly, as only authorized users will have access to the data. The metric will be an indication of whether the API calls were made correctly from the Updox patient portal to the FHIR server. For the data category request, another metric will provide proof that USCDI data is being

Measurement/Metric	Justification
	accessed using the FHIR® Data Access standard required by § 170.315 (g)(8), § 170.315 (g)(9), provide insight into which set of USCDI parameters are accessed the most, and identify any issues related to accessing the USCDI data.
#of apps approved by MaximEyes.com #of apps registered on the developer portal #of patient apps who had accessed the patient data via the APIs #of provider apps who had accessed the patient data via the APIs #of system apps who had accessed the patient data via the APIs # of patients who had accessed their data via the APIs.	This measure determines the number of 3rd party applications that are integrated using the FHIR API interface. The measure also demonstrates the number of API requests and successful responses for accessing single patient data and bulk patient data. This will also demonstrate the number of apps that are in production.

Care Setting(s)

The expectation is that a developer's Real World Testing plan will address each type of clinical setting in which their certified health IT is marketed. Health IT developers are not required to test their certified health IT in every setting in which it is marketed for use. Developers should address their choice of care and/or practice settings to test and provide a justification for the chosen approach.

Note: Health IT developers may bundle products by care setting, criteria, etc. and design one plan to address each, or they may submit any combination of multiple plans that collectively address their products and the care settings in which they are marketed.

List each care setting which is covered by the measure and an explanation for why it is included.

Care Setting	Justification
Optometry and Ophthalmology	MaximEyes.com markets to both optometrists and ophthalmologists, however, we will not be testing those scenarios separately as we have reviewed all the scenarios and it is determined that at this time both optometrists & ophthalmologists would use the functionality in the same way. We mainly market to optometrists, and we have limited ophthalmologists using the application. This will be considered in the future for real world testing as we expand our ophthalmologist customer base.

Expected Outcomes

Health IT developers should detail how the approaches chosen will successfully demonstrate that the certified health IT:

(1) is compliant with the certification criteria, including the required technical standards and vocabulary codes sets;

(2) is exchanging electronic health information (EHI) in the care and practice settings for which it is marketed for use; and/or,

(3) EHI is received by and used in the certified health IT.

(from 85 FR 25766)

Not all of the expected outcomes listed above will be applicable to every certified Health IT Module, and health IT developers may add an additional description of how their measurement approach best addresses the ongoing interoperability functionality of their product(s). Health IT developers could also detail outcomes that should not result from their measurement approach if that better describes their efforts.

Within this section, health IT developers should also describe how the specific data collected from their Real World Testing measures demonstrate expected results. Expected outcomes and specific measures do not necessarily have to include performance targets or benchmarks, but health IT developers should provide context for why specific measures were selected and how the metrics demonstrate individual criterion functionality, EHI exchange, and/or use of EHI within certified health IT, as appropriate.

Measurement/Metric	Expected Outcomes
# of CCDA files sent by the provider via secure email to an external physician, # of CCDAs imported by the physician, # of CCDA files reconciled, # of CCDA files uploaded to the patient portal, # of files viewed, downloaded, transmitted by the patient, # of bulk exports done on the click of export button, # of files exported for each bulk export.	It is expected that providers and patients will be able to share EHI using the transmission mechanisms provided. Some technical errors will be tracked and trended over time
# of times QRDA I files were exported, # of times QRDA III file was exported, # of times QRDA I file was imported.	It is expected that users will be able to export the QRDA category III files.
# of times health care surveys were exported, # of patients the health care surveys were exported for # of eCR files exported , # of patients the eCR was exported for.	It is expected that authorized users will be able to create the Health care surveys and Electronic case reporting. User should be able to export the xml as well.

Measurement/Metric	Expected Outcomes
#of patients searched, # of times the encounter element was fetched and the data that was fetched, # of CCDAs generated.	It is expected that authorized users will be able to access the patient data via API after the correct credentialing is done.
#of apps approved by MaximEyes.com #of apps registered on the developer portal #of patient apps who had accessed the patient data via the APIs #of provider apps who had accessed the patient data via the APIs #of system apps who had accessed the patient data via the APIs # of patients who had accessed their data via the APIs.	It is expected that app developers are actively obtaining patient identifiers, access tokens and are retrieving data.

Schedule of Key Milestones

Include steps within the Real World Testing plan that establish milestones within the process. Include details on how and when the developer will implement measures and collect data. Key milestones should be relevant and directly related to expected outcomes discussed in the next section.

For each key milestone, describe when Real World Testing will begin in specific care settings and the date/timeframe during which data will be collected.

Key Milestone	Care Setting	Date/Timeframe
Release of documentation for the Real-World Testing to be provided to authorized representatives and providers. This may include surveys, specific information on data we will be collecting, what outcomes we are looking for and Customer Agreements.	Optometry	December 15, 2023
Collection of information as laid out by the plan for the period.	Optometry	January 1 – March 31; April 1 – June 30; July 1 – September 30; October 1 – December 31
Planned System updates to allow for collection of data after a SVAP update.	Optometry	N/A
Provide data collection updates to providers and authorized representatives on a regular basis.	Optometry	Quarterly 2024
End of Real-World Testing period/final collection of all data for analysis.	Optometry	January 1, 2025
Analysis and report creation.	Optometry	January 2025

Key Milestone	Care Setting	Date/Timeframe
Submit Real World Testing report to ACB	Optometry	February 15, 2025

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.[2]

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: Shreya Chavan

Authorized Representative Email: shreyac@first-insight.com

Authorized Representative Phone:(503) 567-5352

Authorized Representative Signature: 

Date: 9/15/2023

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