CY 2023 Real World Testing Plan for Criterions

Executive Summary

This is the real world test plan for CY 2023 for Criterions Software, Inc certified EHR solution. It provides the real world test measurements and metrics that meet the intent and objectives of ONC's Condition of Certification and Maintenance of Certification requirement for real world testing (§ 170.405 Real world testing) to evaluate compliance with the certification criteria and interoperability of exchanging electronic health information (EHI) within the care and practice setting which it is targeted for use.

As ONC has stated in its rule, "The objective of real world testing is to verify the extent to which certified health IT deployed in operational production settings is demonstrating continued compliance to certification criteria and functioning with the intended use cases as part of the overall maintenance of a health IT's certification." We have worked toward this objective in designing our test plan and its subsequent real world testing measurements and metrics.

This document builds toward the final testing measurements and metrics we will use to evaluate our product interoperability within production settings. Within each measure, we document planned testing methodology, associated ONC criteria, justification for measurement, expected outcomes from the testing, care settings applied for this measure, and if applicable the number of clients to use our real world testing approach, including how our test cases were created, our selected methodology, the number of client/practice sites to use, and our general approach and justification for decisions.

We have included our timeline and milestones for completing the real world testing in CY 2023, and information about compliance with the Standards Version Advancement Process updates.

A table of contents with hyperlinks is provided later in the plan quick access to any document section, including the testing measurements and metrics found at the end of this document. Our signed attestation of compliance with the real world testing requirements is on the following page.

Developer Attestation

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.

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DATE: 10/25/2022

General Information

Plan Report ID Number: Criterions-RWT-2023

Developer Name: Criterions Software Inc

Product Name(s): Criterions EHR

Version Numbers(s): 4

Certified Health IT Criteria: 315(b)(1)-(3), (b)(6), (c)(1)-(3), (e)(1), (f)(1), (f)(5), (g)(7)-(9)

Product List (CHPL) ID(s) and Link(s):

- 15.04.04.2705.Crit.04.00.1.191111
- https://chpl.healthit.gov/#/listing/10171

Developer Real World Testing Page URL: https://criterions.com/rwt

Timeline and Milestones for Real World Testing CY 2023

- 1Q-2023: Begin communication with clients to ask for their support and participation in real world testing. The goal is to have a sufficient number of clients committed for real world testing by the end of 1Q-2023.
- 2Q-3Q 2023. During the 2nd and 3rd quarter of CY 2023, the majority real world testing with clients will be scheduled and performed. We will attempt to do the eCQM testing in early 2023 to align with the MIPS submission window. Results will be documented in the test results section of the test methods and ultimately used to build the test report. If any non-compliances are observed, we will notify the ONC-ACB of the findings and make the necessary changes required.
- 4Q-2023. During the last quarter of the year, the CY 2024 real world test plan will be completed according to ONC and ONC-ACB requirements and expectations. Test plan will be prepared for submission before the end of the year.

Standards Updates (SVAP and USCDI)

Before the end of CY 2022, we will certify and update the latest version of our EHR to support USCDI v1 and deploy it to production.

Standard (and version)	USCDI v1
Updated certification criteria and associated product	Criterions for 315(b)(1), (b)(2), (e)(1), (g)(9), (g)(10)
Health IT Module CHPL ID	TBD
Method used for standard update	ONC Cures Update Testing/Certification
Date of ONC-ACB notification	Before end of CY 2022
Date of customer notification (SVAP only)	N/A
Conformance measure	Measure #1, #2, #6, #9
USCDI-updated certification criteria (and USCDI version)	USCDI v1 for 315(b)(1), (b)(2), (e)(1), (g)(9), (g)(10)

For our eCQM submission to CMS, we will be updating to the newest CMS implementation guide before the end of CY 2022 as part of our Cures update certification.

Standard (and version)	CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2022 (December 2021)
Updated certification criteria and associated product	Criterions for 315(c)(3)
Health IT Module CHPL ID	TBD
Method used for standard update	ONC Cures Update Testing/Certification
Date of ONC-ACB notification	Before end of CY 2022
Date of customer notification (SVAP only)	N/A
Conformance measure	Measure #5

Real World Testing Measurements

The measurements for our real world testing plan are described below. Each measurement contains:

- Associated ONC criteria
- Testing Methodology used
- Description of the measurement/metric
- Justification for the measurement/metric
- Expected outcomes in testing for the measurement/metric
- Number of client sites to use in testing (if applicable)
- Care settings which are targeted with the measurement/metric

In each measurement evaluate, we elaborate specifically on our justification for choosing this measure and the expected outcomes. All measurements were chosen to best evaluate compliance with the certification criteria and interoperability of exchanging electronic health information (EHI) within the certified EHR.

Testing Methodologies

For each measurement, a testing methodology is used. For our test plan, we use the following methodologies.

Reporting/Logging: This methodology uses the logging or reporting capabilities of the EHR to examine functionality performed in the system. A typical example of this is the measure reporting done for the automate measure calculation required in 315(g)(2), but it can also be aspects of the audit log or customized reports from the EHR. This methodology often provides historical measurement reports which can be accessed at different times of the year and evaluate interoperability of EHR functionality, and it can serve as a benchmark for evaluating real world testing over multiple time intervals.

Compliance and/or Tool: This methodology uses inspection to evaluate if EHR is compliant to the ONC criteria requirements. It can be done through 1-v-1 inspection testing or utilize various tools to measure or evaluate compliance and interoperability. If an EHR Module capabilities is not widely used in production by current users, compliance inspection can provide assurance criteria is working as previously certified.

Survey/Self-Test: This methodology evaluates interoperability and compliance of EHR Module capabilities through feedback from users. ONC has recognized that self-testing can be a viable method for evaluation and compliance, and this methodology can provide insight into how clinicians employ and use a feature which reveals actual value and impact of interoperability of the EHR Module.

Number of Clients Sites

Within each measure, we note the minimum number of clients or client sites we plan to use for this measure evaluation. The numbers vary depending on the methodology as well as overall use of the associated EHR Module criteria by our users. For criteria that are not widely used by our customer base, we may test the respective measure in our own production-sandbox environment given lack of customer experience with the criteria functionality.

Care and Practice Settings Targeted

Our EHR is primarily targeted to general ambulatory practices covering a variety of care settings including orthopedics, primary care, dermatology, cardiology, neurology, OBGYN, ENT, pulmonology, pediatrics, and multispecialty. However, they all utilize our ONC certified capabilities common methods associated with ambulatory care. Our measures were design for these ambulatory settings in mind. In each measure, we do also address the care settings targeted and note any necessary adjustment or specific factor to consider with this specific measure.

RWT Measure #1. Number of Transition of Care C-CDAs Successfully Sent

Associated Criteria: 315(b)(1)

Testing Methodology: Reporting/Logging

Measurement Description

This measure is tracking and counting how many C-CDAs are created and successfully sent from the EHR Module to a 3rd party via Direct messaging during a transition of care event over the course of a given interval.

Measurement Justification

This measure will provide a numeric value to indicate both the how often this interoperability feature is being used as well as its compliance to the requirement. An increment to this measure indicates that the EHR can create a C-CDA patient summary record, including ability to record all clinical data elements, and by sending the C-CDA patient summary record, the EHR demonstrates successful interoperability of an exchanged patient record with a 3rd party. This measurement shows support for Direct Edge protocol in connecting to a HISP for successful transmission.

Measurement Expected Outcome

Criterions will track number of C-CDA files sent electronically via HISP and/or uploaded to RHIOs.

The measurement will produce numeric results over a given interval. We will utilize various reports and audit logs, including Automated Measure (315.g.2) reports, to determine our measure count.

We will capture this information from our system over a period of a minimum of three (3) months to provide an accurate sample of real world interoperability.

A successful measure increment indicates compliance to the underlying ONC criteria. It will show that the EHR can create the C-CDA patient summary record, including record required clinical data elements. In sending the C-CDA patient summary record, the EHR will demonstrate ability to confirm successful interoperability of an exchanged patient record with a 3rd party, including support for Direct Edge protocol in connecting to a HISP. Successfully completing this measure also implies users have a general understanding of the EHR functional operations for this EHR Module and an overall support for the user experience while not completing this measure may indicate lack of understanding or possibly lack of use or need for this functionality.

We will use the measure count to establish a historic baseline of expected interoperability use so it can be used in subsequent real world testing efforts.

Care Settings and Number of Clients Site to Test

We designed this measure for all the ambulatory care settings that we support: orthopedics, primary care, dermatology, cardiology, neurology, OBGYN, ENT, pulmonology, pediatrics, and multispecialty. We will test a minimum of ten (10) client practices. This number covers a sufficient percentage of existing practices to provide a viable sample of users of the certified EHRs.

RWT Measure #2. Number of C-CDAs Received and/or Incorporated

Associated Criteria: 315(b)(2)

Testing Methodology: Reporting/Logging

Measurement Description

This measure is tracking and counting how many C-CDAs are successfully received and/or incorporated upon receipt from a 3rd party via Direct messaging during a transition of care event over the course of a given time frame.

Measurement Justification

This measure will provide a numeric value to indicate both the how often this interoperability feature is being used as well as its compliance to the requirement. An increment to this measure indicates that the EHR can receive a C-CDA patient summary record, and by incorporating the C-CDA patient summary record, the EHR demonstrates successful interoperability of problems, medications, and medication allergies of patient record with a 3rd party. This measurement shows support for Direct Edge protocol in connecting to a HISP for successful transmission.

Measurement Expected Outcome

The measurement will produce numeric results over a given time frame interval. We will utilize various reports and audit logs, including Automated Measure (315.g.2) reports, to determine our measure count.

If any errors or very low numeric counts are encountered, we will investigate further.

We will capture this information from our system over a period of a minimum of three (3) months to provide an accurate sample of real world interoperability.

A successful measure increment indicates compliance to the underlying ONC criteria. It will show that the EHR can create the EHR can receive a C-CDA patient summary record. In incorporating the C-CDA patient summary record, the EHR will demonstrate successful interoperability of problems, medications, and medication allergies of patient record with a 3rd party, including support for Direct Edge protocol in connecting to a HISP. Successfully completing this measure also implies users have a general understanding of the EHR functional operations for this EHR Module and an overall support for the user experience while not completing this measure may indicate lack of understanding or possibly lack of use or need for this functionality.

We will use the measure count to establish a historic baseline of expected interoperability use so it can be used in subsequent real world testing efforts.

Care Settings and Number of Clients Site to Test

We designed this measure for all the ambulatory care settings that we support: orthopedics, primary care, dermatology, cardiology, neurology, OBGYN, ENT, pulmonology, pediatrics, and multispecialty. We will test a minimum of ten (10) client practices. This number covers a sufficient percentage of existing practices to provide a viable sample of users of the certified EHRs.

RWT Measure #3. Number of NewRx Prescriptions Messages Successfully Sent

Associated Criteria: 315(b)(3)

Testing Methodology: Reporting/Logging

Measurement Description

This measure is tracking and counting how many NewRx electronic prescriptions were created and successfully sent from the EHR Module to a pharmacy destination over the course of a given interval.

Measurement Justification

This measure will provide a numeric value to indicate both the how often this interoperability feature is being used as well as its compliance to the requirement. An increment to this measure indicates that the EHR can create a NewRx SCRIPT electronic prescription message and transmit it to a pharmacy, typically via the Surescripts Network.

Measurement Expected Outcome

The measurement will produce numeric results over a given interval. We will utilize various reports and audit logs, including Automated Measure (315.g.2) reports, to determine our measure count. We will create a success rate of electronic prescriptions and note any transaction failures.

We will capture this information from our system over a period of a minimum of three (3) months to provide an accurate sample of real world interoperability.

A successful measure increment indicates compliance to the underlying ONC criteria. It will show that the EHR can create the NewRx message and send over a production network, like the Surescripts Network, to a pharmacy. Successfully completing this measure also implies users have a general understanding of the EHR functional operations for this EHR Module and an overall support for the user experience while not completing this measure may indicate lack of understanding or possibly lack of use or need for this functionality.

We will use the measure count to establish a historic baseline of expected interoperability use so it can be used in subsequent real world testing efforts.

Care Settings and Number of Clients Site to Test

We designed this measure for all the ambulatory care settings that we support: orthopedics, primary care, dermatology, cardiology, neurology, OBGYN, ENT, pulmonology, pediatrics, and

multispecialty. We will test a minimum of ten (10) client practices. This number covers a sufficient percentage of existing practices to provide a viable sample of users of the certified EHRs.

RWT Measure #4. Number of Patient Batch Exports Run

Associated Criteria: 315(b)(6)

Testing Methodology: Reporting/Logging

Measurement Description

This measure is tracking and counting how many batch exports of C-CDAs were successfully performed by the EHR Module over the course of a given interval.

Measurement Justification

This measure will provide a numeric value to indicate both the how often this interoperability feature is being used as well as its compliance to the requirement. An increment to this measure indicates that the EHR can create a batch export of multiple C-CDA patient summary records.

Measurement Expected Outcome

The measurement will produce numeric results over a given interval. We will utilize database queries to determine our measure count. If any errors or very low numeric counts are encountered, we will investigate further.

We will capture this information from our system over a period of a minimum of three (3) months to provide an accurate sample of real world interoperability.

A successful measure increment indicates compliance to the underlying ONC criteria. It will show that the EHR can create a batch export of multiple C-CDA patient summary records, which can be used in means of health IT interoperability. Successfully completing this measure also implies users have a general understanding of the EHR functional operations for this EHR Module and an overall support for the user experience while not completing this measure may indicate lack of understanding or possibly lack of use or need for this functionality.

We will use the measure count to establish a historic baseline of expected interoperability use so it can be used in subsequent real world testing efforts.

Care Settings and Number of Clients Site to Test

We designed this measure for all the ambulatory care settings that we support: orthopedics, primary care, dermatology, cardiology, neurology, OBGYN, ENT, pulmonology, pediatrics, and multispecialty. We will test a minimum of ten (10) client practices. This number covers a sufficient percentage of existing practices to provide a viable sample of users of the certified EHRs.

RWT Measure #5. Number of Quality Measures Successfully Reported on to CMS

Associated Criteria: 315(c)(1)-(c)(3)

Testing Methodology: Reporting/Logging/Survey

Measurement Description

This measure is tracking and counting how many eCQM quality measures were successfully reported on by the EHR Module to CMS over the course of a given interval.

Measurement Justification

This measure will provide a count and list of electronic clinical quality measures (eCQMs) which are calculated and submitted to CMS for a given program, like MIPS. Clinical quality measures are only used for the respective CMS programs and any production measures should utilize submission to CMS. Because CQM criteria, 315(c)(1)-(c)(3), all work collectively together in the eCQM functionality of the EHR Module, this measurement is used for all three.

Measurement Expected Outcome

The measurement will a count and list of eCQMs submitted to CMS over a given interval. We will utilize various reports and audit logs to determine our measure count.

We will capture this information from our system over the CMS MIPS reporting period of full calendar year.

A successful measure submission indicates compliance to the underlying ONC criteria. It will show that the EHR can do calculations on the eCQM and survey clients to confirm that they are accepted by CMS. Successfully completing this measure also implies users have a general understanding of the EHR functional operations for this EHR Module and an overall support for the user experience while not completing this measure may indicate lack of understanding or possibly lack of use or need for this functionality.

We will use the measure result to establish a historic baseline of expected interoperability use so it can be used in subsequent real world testing efforts.

Care Settings and Number of Clients Site to Test

We designed this measure for all the ambulatory care settings that we support: orthopedics, primary care, dermatology, cardiology, neurology, OBGYN, ENT, pulmonology, pediatrics, and multispecialty. We will test a minimum of ten (10) client practices. This number covers a

sufficient percentage of existing practices to provide a viable sample of users of the certified EHRs.

RWT Measure #6. Number of Patients Who Accessed/Logged in to Portal

Associated Criteria: 315(e)(1)

Testing Methodology: Reporting/Logging

Measurement Description

This measure is tracking and counting how many patients are successfully logged into and accessed their patient portal account over the course of a given interval.

Measurement Justification

This measure will provide a numeric value to indicate both the how often this interoperability feature is being used as well as its compliance to the requirement. An increment to this measure indicates that patients can log into their patient portal to view, download, or transmit their health data.

Measurement Expected Outcome

The measurement will produce numeric results over a given interval. We will utilize various reports and audit logs, including Automated Measure (315.g.2) reports, to determine our measure count.

We will track the number of patients who logged into the portal, as well as total number of logins, and contrast that with the patients seen by the respective providers during that same time.

We will capture this information from our system over a period of a minimum of three (3) months to provide an accurate sample of real world interoperability.

A successful measure increment indicates compliance to the underlying ONC criteria. It will show that patients can log into their patient portal to view, download, or transmit their health data. Successfully completing this measure also implies users have a general understanding of the EHR functional operations for this EHR Module and an overall support for the user experience while not completing this measure may indicate lack of understanding or possibly lack of use or need for this functionality.

We will use the measure count to establish a historic baseline of expected interoperability use so it can be used in subsequent real world testing efforts.

Care Settings and Number of Clients Site to Test

We designed this measure for all the ambulatory care settings that we support: orthopedics, primary care, dermatology, cardiology, neurology, OBGYN, ENT, pulmonology, pediatrics, and multispecialty. We will test a minimum of ten (10) client practices. This number covers a sufficient percentage of existing practices to provide a viable sample of users of the certified EHRs.

RWT Measure #7. Number of Immunization Messages Successfully Sent to IIS/Immunization Registries

Associated Criteria: 315(f)(1)

Testing Methodology: Reporting/Logging

Measurement Description

This measure is tracking and counting how many immunization messages are created and successfully sent from the EHR Module to an IIS/immunization registry over the course of a given interval.

Measurement Justification

This measure will provide a numeric value to indicate both the how often this interoperability feature is being used as well as its compliance to the requirement. An increment to this measure indicates that the EHR can create an immunization message, including ability to record all clinical data elements, and by sending the message, the EHR demonstrates successful interoperability with an IIS/immunization registry.

Measurement Expected Outcome

The measurement will produce numeric results over a given interval. We will utilize various reports and audit logs, to determine our measure count.

We will capture this information from our system over a period of a minimum of three (3) months to provide an accurate sample of real world interoperability.

A successful measure increment indicates compliance to the underlying ONC criteria. It will show that the EHR can create the HL7 immunization record, including ability to record the required clinical data elements. In sending the immunization message, the EHR will demonstrate ability to confirm successful interoperability of patient's immunization data to an IIS/immunization registry. Successfully completing this measure also implies users have a general understanding of the EHR functional operations for this EHR Module and an overall support for the user experience while not completing this measure may indicate lack of understanding or possibly lack of use or need for this functionality.

We will use the measure count to establish a historic baseline of expected interoperability use so it can be used in subsequent real world testing efforts.

Care Settings and Number of Clients Site to Test

We designed this measure for all the primary care and pediatrics practices we serve as they are the only ones who regularly use immunization functionality. We will test a minimum of ten (10) client practices. This number covers a sufficient percentage of existing practices to provide a viable sample of users of the certified EHRs.

RWT Measure #8. Number of Patient Immunization History Queries Sent

Associated Criteria: 315(f)(1)

Testing Methodology: Reporting/Logging

Measurement Description

This measure is tracking and counting how many patient immunization history queries are created and successfully sent from the EHR Module to an IIS/immunization registry over the course of a given interval.

Measurement Justification

This measure will provide a numeric value to indicate both the how often this interoperability feature is being used as well as its compliance to the requirement. An increment to this measure indicates that the EHR can create a patient immunization history query message, and by sending the message, the EHR demonstrates successful interoperability with an IIS/immunization registry.

Measurement Expected Outcome

The measurement will produce numeric results over a given interval. We will utilize various reports and audit logs, to determine our measure count.

We will capture this information from our system over a period of a minimum of three (3) months to provide an accurate sample of real world interoperability.

A successful measure increment indicates compliance to the underlying ONC criteria. It will show that the EHR can create the HL7 immunization history query of a patient. In sending the immunization message, the EHR will demonstrate ability to confirm successful interoperability with an IIS/immunization registry. Successfully completing this measure also implies users have a general understanding of the EHR functional operations for this EHR Module and an overall support for the user experience while not completing this measure may indicate lack of understanding or possibly lack of use or need for this functionality.

We will use the measure count to establish a historic baseline of expected interoperability use so it can be used in subsequent real world testing efforts.

Care Settings and Number of Clients Site to Test

We designed this measure for all the primary care and pediatrics practices we serve as they are the only ones who regularly use immunization functionality. We will test a minimum of ten (10)

client practices. This number covers a sufficient percentage of existing practices to provide a viable sample of users of the certified EHRs.

RWT Measure #9. Number of Applications/3rd party Systems that are Accessing FHIR API Server

Associated Criteria: 315(g)(7), (g)(9), (g)(10)

Testing Methodology: Reporting/Logging

Measurement Description

This is a measure to determine how many different systems or applications are connecting to our EHR via the API. We will look over the course of a minimum of six (6) months to gauge registered applications and active use.

Measurement Justification

This measure will determine how many 3rd party systems or applications are integrated and using the EHR's FHIR API interface. This measure will allow us to verify our certified API is working with 3rd party applications to access USCDI patient data.

Measurement Expected Outcome

The measurement will provide a count of FHIR application applications which have registered with our server for patient access as well as applications actively connecting to our FHIR server. We will utilize our FHIR API form which developers use to request API access as well as additional reports and audit logs to determine the number of API applications enabled for our system.

The answer will provide insight into how both patients and clinicians view both the use and value of this interoperability feature.

Care Settings and Number of Clients Site to Test

We designed this measure to test the ambulatory care setting that we support and target.

RWT Measure #10. Number of Different Electronic Case Public Registries Engaged and Connected

Associated Criteria: 315(f)(5)

Testing Methodology: Survey

Measurement Description

This is a survey measure to determine the number of electronic case public health registries you use.

Measurement Justification

This measure will survey users to determine real world interoperability and usability, specifically many different public health electronic case registries are used by the provider. As we are not sure if our physician community is submitting electronic case reporting through our EHR, we will survey them to determine its interoperability status.

A survey can often provide more information on the impact and value of an interoperability element than a standard software test evaluation. This survey measure will the number and names of electronic reportable lab public health registries which are integrated with the EHR.

Measurement Expected Outcome

The user will be asked the survey question and given the survey answer choices below:

- Numeric answer to the question, and if willing, the names of the other systems.
- Have you experienced any problems with connections?

The answer will provide insight into how clinicians view both the use and value of this interoperability feature. For example, response may show that additional training is needed to better utilize the feature or that it is not currently utilized as currently designed. It will provide a benchmark for evaluate future surveys as well as to share insight into any new development for improvements or enhancements of the health IT system.

Number of Clients Site to Test

Our intention is to survey an appropriate number of our user community to gauge an adequate sample size. We will look to speak with physicians across our various care settings to best understand the interoperability status of this feature.