

# CY 2023 Real World Testing Plan for TenEleven Group electronic Clinical Record

# **Executive Summary**

This is the real world test plan for CY 2023 for TenEleven Group certified EHR solution, electronic Clinical Record (eCR). 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 use case, we document our testing methodology for the measure/metric we plan to employ. We also include the associated ONC criteria, our justification for measurement selection, our expected outcomes from the testing, the care settings applied for this measure, and if applicable the number of clients to use in our real world testing.

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 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 11 / 01 / 2022



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# **General Information**

Plan Report ID Number: eCR-RWT-2023

Developer Name: TenEleven Group

Product Name(s): electronic Clinical Record (eCR)

Version Numbers(s): 2.23

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

(g)(7)-(9)

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

• 15.04.04.2861.Elec.22.00.1.181231

• <a href="https://chpl.healthit.gov/#/listing/9831">https://chpl.healthit.gov/#/listing/9831</a>

Developer Real World Testing Page URL: https://10e11.com/onc-real-world-test/



# 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 2<sup>nd</sup> and 3<sup>rd</sup> quarter of CY 2023, the real world testing with clients will be scheduled and performed. It is expected that a preparatory call will be done with clients to prepare them for testing activities. 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.
- 1Q-2024. Submit RWT Test Report to ONC-ACB.



# Standards Version Advancement Process (SVAP) Updates

For CY 2023, we are not planning to make any version updates on approved standards through the SVAP process. We plan on implementing USCDI v1 in our C-CDAs and API before the end of the 2022 year, but we have not finalized an exact date for rollout.

Standard (and version)	N/A
Updated certification criteria and associated product	N/A
Health IT Module CHPL ID	N/A
Method used for standard update	N/A
Date of ONC-ACB notification	N/A
Date of customer notification (SVAP only)	N/A
Conformance measure	N/A
USCDI-updated certification criteria (and USCDI version)	N/A



# **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 Health IT Module capabilities is not widely used in production by current users, compliance inspection can provide assurance criteria is working as previously certified.

#### **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 Health IT 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 and behavioral health practices, and our measures were design for this setting 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 Health IT Module to a 3<sup>rd</sup> party via Direct messaging during a transition of care event over the course of a given interval.

The interval for this measure will be a minimum of 3 months.

#### 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

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.

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 Health IT 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



#### 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 interval.

The interval for this measure will be a minimum of 3 months.

#### 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 interval. We will utilize various reports and audit logs, including Automated Measure (315.g.2) reports, to determine our measure count.

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 Health IT 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



# 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 Health IT Module to a pharmacy destination over the course of a given interval.

The interval for this measure will be a minimum of 3 months.

#### 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.

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 Health IT 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





# RWT Measure #4. Number of Quality Measures Successfully Reported on to CMS

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

Testing Methodology: Reporting/Logging

#### Measurement Description

This measure is tracking and counting how many eCQM quality measures were successfully reported on by the Health IT 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 Health IT 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.

A successful measure submission indicates compliance to the underlying ONC criteria. It will show that the EHR can do calculations on the eCQM and that they are accepted by CMS. Successfully completing this measure also implies users have a general understanding of the EHR functional operations for this Health IT 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



#### RWT Measure #5. Number of Patients Given Access to Portal

Associated Criteria: 315(e)(1)

Testing Methodology: Reporting/Logging

#### Measurement Description

This measure is tracking and counting how many patients are given login access to their patient portal account over the course of a given interval.

The interval for this measure will be a minimum of 3 months.

#### Measurement Justification

This measure will provide a numeric value to indicate how often this interoperability feature is being used. An increment to this measure indicates that the EHR can supply patient health data to the patient portal and provide an account for the patient to use in accessing this 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.

A successful measure increment indicates compliance to the underlying ONC criteria. It will show that the EHR can submit patient health data to the patient portal on a regular and consistent basis as well provide an account for the patient to use in accessing this data. Successfully completing this measure also implies users have a general understanding of the EHR functional operations for this Health IT 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



### RWT Measure #6. Number of Immunization Registries Engaged

Associated Criteria: 315(f)(1)

Testing Methodology: Reporting/Logging

#### Measurement Description

This measure is tracking and counting how many immunization public health registries are engaged and exchanging data with the client site.

#### 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 has established and can maintain a bi-direction exchange with the public health registry. This engagement demonstrates the Health IT Module's compliance with the ONC criteria and meeting real world use for client customers.

#### 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 expect any public health registry to be able to successfully connect and exchange with the EHR and observing these connections will 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 message, the EHR will demonstrate ability to confirm successful interoperability of patient's data to the public health registry.

For connected IIS/immunization registries, we expect very few errors or downtime due to the Health IT Module's functionality.

#### Care Settings and Number of Clients Site to Test



# RWT Measure #7. Number of Syndromic Surveillance Registries Engaged

Associated Criteria: 315(f)(2)

Testing Methodology: Reporting/Logging

#### Measurement Description

This measure is tracking and counting how many syndromic surveillance public health registries are engaged and exchanging data with the client site.

#### 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 has established and can maintain an exchange with the public health registry. This engagement demonstrates the Health IT Module's compliance with the ONC criteria and meeting real world use for client customers.

#### 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 expect any public health registry to be able to successfully connect and exchange with the EHR and observing these connections will indicates compliance to the underlying ONC criteria. It will show that the EHR can create the HL7 syndromic surveillance record, including ability to record the required clinical data elements. In sending the message, the EHR will demonstrate ability to confirm successful interoperability of patient's data to the public health registry.

For connected registries, we expect very few errors or downtime due to the Health IT Module's functionality.

#### Care Settings and Number of Clients Site to Test



# RWT Measure #8. Number of Electronic Reportable Lab Registries Engaged

Associated Criteria: 315(f)(3)

Testing Methodology: Reporting/Logging

#### Measurement Description

This measure is tracking and counting how many reportable lab public health registries are engaged and exchanging data with the client site.

#### 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 has established and can maintain an exchange with the public health registry. This engagement demonstrates the Health IT Module's compliance with the ONC criteria and meeting real world use for client customers.

#### 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 expect any public health registry to be able to successfully connect and exchange with the EHR and observing these connections will indicates compliance to the underlying ONC criteria. It will show that the EHR can create the HL7 electronic reportable lab record, including ability to record the required clinical data elements. In sending the message, the EHR will demonstrate ability to confirm successful interoperability of patient's data to the public health registry.

For connected registries, we expect very few errors or downtime due to the Health IT Module's functionality.

#### Care Settings and Number of Clients Site to Test



# RWT Measure #9. Number of Electronic Case Reporting Registries Engaged

Associated Criteria: 315(f)(5)

Testing Methodology: Reporting/Logging

#### Measurement Description

This measure is tracking and counting how many electronic case reporting public health registries are engaged and exchanging data with the client site.

#### 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 has established and can maintain a direction exchange with the public health registry. This engagement demonstrates the Health IT Module's compliance with the ONC criteria and meeting real world use for client customers.

#### 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 expect any public health registry to be able to successfully connect and exchange with the EHR and observing these connections will indicates compliance to the underlying ONC criteria. It will show that the EHR can create the electronic case reporting message, including ability to record the required clinical data elements. In sending the message, the EHR will demonstrate ability to confirm successful interoperability of patient's data to the public health registry.

For connected registries, we expect very few errors or downtime due to the Health IT Module's functionality.

#### Care Settings and Number of Clients Site to Test



# RWT Measure #10. Number of Applications/3rd Party Systems using API Capabilities

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

Testing Methodology: Reporting/Logging and Survey/Self-Test

#### Measurement Description

This measure will determine how many 3<sup>rd</sup> 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 3<sup>rd</sup> party applications to access USCDI patient data.

#### Measurement Justification

This measure will determine how many 3<sup>rd</sup> 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 3<sup>rd</sup> party applications to access USCDI patient data.

#### Measurement Expected Outcome

The measurement will provide a count of FHIR 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. We will also query clinician users to determine the API applications they have approved for use on their system.

We do not believe many of our clients will be using API capabilities next year, but for those who do, we expect it work and return appropriate clinical data.

#### Care Settings and Number of Clients Site to Test



# RWT Measure #11. Compliance of Data Export C-CDA Export and C-CDA Scorecard Average Score

Associated Criteria: 315(b)(6)

Testing Methodology: Compliance and Tool

#### Measurement Description

This measure is tracking compliance of the Health IT Module criteria functionality of creating a batch export of C-CDAs and measuring its C-CDA Scorecard average.

#### Measurement Justification

To our knowledge, our customer rarely, if ever, use this Health IT Module so we will evaluate it via a compliance inspection.

This measure will provide assurance of compliance to the Health IT Module criteria, specifically ability to create a batch export of C-CDA patient records and evaluate it against the ONC C-CDA Scorecard tool. The C-CDA scorecard is designed for production use and measures how artifacts created by health IT compare against the HL7 C-CDA implementation guide and HL7 best practices.

The Scorecard will both indicate any C-CDA errors as well provide a numeric scoring result to indicate how well our C-CDA complies with certification requirements and supports interoperability within production setting.

To avoid disclosing PHI, we will only work with test patients from the actual production environment or an appropriately production-mirrored environments to best evaluate production capabilities available to end users.

#### Measurement Expected Outcome

The user with special access rights, like an admin, selects batch patient option to export all selected record as CCD C-CDA. The user must be able to do this without any developer assistance. The user selects a timeframe period to export patient summaries and a location for the export file to be saved. The EHR will create the batch export of C-CDA files. We will run some C-CDAs through the Scorecard tool to obtain a result. We will also confirm the process and steps done by the user meet the criteria requirements of the Health IT Module and works as expected in production as in a controlled test environment.

A high score from the Scorecard indicates strong support for interoperability, and a lower score indicates opportunity for improvement. We will use this measure 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



### RWT Measure #12. Compliance of Privacy Security Tag Features

Associated Criteria: 315(b)(7)-(b)(8)

Testing Methodology: Compliance

#### Measurement Description

This measure is tracking compliance of the Health IT Module criteria functionality of creating a C-CDA with privacy security tags.

#### Measurement Justification

To our knowledge, our customer rarely, if ever, use this Health IT Module so we will evaluate it via a compliance inspection.

This measure will provide assurance of compliance to the Health IT Module criteria, specifically ability to create a C-CDA with document-level privacy tags to restrict content access.

To avoid disclosing PHI, we will only work with test patients from the actual production environment or an appropriately production-mirrored environments to best evaluate production capabilities available to end users.

#### Measurement Expected Outcome

The user will use the EHR functions to enable document-level security or select a patient with this setting enabled. The user exports a C-CDA CCD from the patient record, and the EHR creates the CCD with document-level tagged restricted content according to the HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1. We will also confirm the process and steps done by the user meet the criteria requirements of the Health IT Module and works as expected in production as in a controlled test environment.

#### Care Settings and Number of Clients Site to Test



#### RWT Measure #13. Compliance of Care Plan C-CDA

Associated Criteria: 315(b)(9)

Testing Methodology: Compliance and Tool

#### Measurement Description

This measure is tracking compliance of the Health IT Module criteria functionality of creating a Care Plan C-CDA.

#### Measurement Justification

To our knowledge, our customer rarely, if ever, use this Health IT Module so we will evaluate it via a compliance inspection.

This measure will provide assurance of compliance to the Health IT Module criteria, specifically ability to create a Care Plan document C-CDA, which represents a patient's and care team members' prioritized concerns, goals, and planned interventions. We will also evaluate it against the <a href="ONC C-CDA Scorecard tool">ONC C-CDA Scorecard tool</a>. The C-CDA scorecard is designed for production use and measures how artifacts created by health IT compare against the HL7 C-CDA implementation guide and HL7 best practices.

To avoid disclosing PHI, we will only work with test patients from the actual production environment or an appropriately production-mirrored environments to best evaluate production capabilities available to end users.

#### Measurement Expected Outcome

The user will have the EHR create Care Plan document C-CDA from a patient record containing clinical data elements required in the criteria, specifically information associated with a care plan including goals, health concerns, health status, outcomes, and intervention information. User can access and change this information before saving the content. We will run C-CDA through the Scorecard tool to obtain a result. We will also confirm the process and steps done by the user meet the criteria requirements of the Health IT Module and works as expected in production as in a controlled test environment.

A high score from the Scorecard indicates strong support for interoperability, and a lower score indicates opportunity for improvement. We will use this measure 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