Real World Testing Plan

GENERAL INFORMATION

Plan Report ID Number: PRO20152021

Developer Name: **Procentive**

Product Name(s): **Procentive**

Version Number(s): 2015

Certified Health IT Product List (CHPL) ID(s): 15.04.04.2214.Proc.14.00.0.180427

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

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

Procentive's overall approach to Real World Testing, will use data to demonstrate interoperability criterion by measuring relevant tasks and successful collection of specific auditable data associated with each certification requirement.

Measures will align with the elements within a Real World Testing plan including certification requirements and clinical settings.

Note: Procentive's Real World Testing plan will address certification criteria for multiple care settings

Quantitative Usability testing is a widely practiced industry standard recommended by research-based design experts such as the Nielsen Normal Group, and can provide summative evidence that our products allow users to complete relevant tasks analogous to their real world domain requirements. Users will be asked to complete a set of tasks that represent real-world activities using example data, while a researcher will observe and document the execution of said tasks. The rate of successful completion of these representative tasks (captured as quantitative and qualitative data) can be extrapolated to user performance with the product in the field.

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 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/Associated Certification Criteria/ Justification for Selected Measurement/Metric

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

Associated Certification Criteria	Measurement/Metric	Description	Justification
b.1 Transitions of Care	1. Over two weeks' time, observe the capture in the audit log of the number of messages with CCDAs attached successfully sent	The user will be sending and receiving C-CDA's to demonstrate that the system successfully exchanges the certified C-CDA with another outside provider.	The system logs the sending information in the user interface to confirm the status of the message. Observing the number of messages with the correct information will verify that the system performed as expected and meets the ONC criteria.
b.2 Clinical Information Reconciliation and Incorporation	1. Count number of times reconciliation of medications, allergies and problems is performed over a two-week time frame	The user will reconcile the C-CDA received in b.1 with an existing client in the database to demonstrate that the system can successfully import and reconcile Problems, Medications, and Medication Allergies from an outside provider.	The change log captures modifications made to all fields related to a client*. After the C-CDA is reconciled, viewing the modification logs within the change log will verify that the system performed as expected and meets the ONC criteria.
b.6 Data Export	1. Count the number of times data export is performed over a two-week time frame.	The user will generate a C-CDA over a period of two-weeks to demonstrate that	The audit log captures count of number of C-CDAs generated for both single and a group of clients*.

		the system can successfully export patient data.	
c.1 Record and Export	1. Count of unique customers that have exported at least one QRDA I document in Q1 at all sites.	The user will add data for clients in the system and export at least one QRDA to demonstrate successful recording and export of the CQM's	Counting generated QRDAs shows successful export.
c.2 Import and Calculate	1. Count number of imported QRDAs which demonstrates successful calculation of CQM's based on imported file	The user will import an outside QRDA to demonstrate successful import and calculation of CQM's.	Demonstrating that the measure calculations change after the import of a QRDA will verify that the system successfully receives CQM data from outside sources and calculates correctly.
c.3 Report	1. Count number of QRDA are exported with correct CQM calculation	The user successfully creates the data file for report transmission.	Generating the data file for report transmission and viewing CQM's verifies the system performs as expected.
e.1 VDT	1. Count number of instances a C-CDA View, C-CDA Download, and C-CDA Transmit for the user	The client (patient) will view, download, and send C-CDAs from a patient portal to demonstrate that the system allows the client to have visibility, access, and control of their data.	The Audit Log captures the number of CCDAs viewed, downloaded and transmitted of a C-CDA from the patient portal. Counting the number of CCDAs with the correct date/time stamp and user of these activities appear in the Audit Log will verify that the system performs as expected

			and meets the ONC criteria.
f.1 Transmission to Immunization Registries	1. Count of user organizations live with this interface. For immunizations, all immunization fields (Start of Vaccine Date, Start of Vaccine Time, Ordering Provider, Administering Provider, Administered Test Code, Administered Test Code System, Procedure (name of vaccine), Amount, Units, Lot Number, Manufacturer Name, Manufacturer Code, Date Time Expiration, Route, Body Site, Order ID, Substance/treatment Refusal, Administration Notes, and Status) are tracked as "add" in the audit log 2. Count of interface transactions	The user will add an immunization record in the system to demonstrate that the system successfully captures additions to records to be sent to a registry.	The count of organizations live with this interface demonstrates active use of this registry.
f.2 Transmission to Public Health Agencies-Syndromic Surveillance	1. Count of user organizations live with this interface and 90% all observation fields (Date Taken, Observation Type, Observation Value, Coding System, Code, Alt Code, Alt Value, Units Type, Notes, Observation Result, and Status) contain all expected data elements 2. Count of interface transactions	The user will add at least one new observation records in the system to demonstrate that the system successfully captures additions to records to be sent to a registry.	Count of all user organizations live with this registry and data completeness of the fields in the Syndromic Surveillance screen will verify that the system performs as expected and meets the ONC criteria.

*client=patient
** client portal = patient portal

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
Mental Health-Outpatient	This care setting encompasses nearly 40% of Procentive's user base. Including this care setting will demonstrate that the system works in the real world for many of our users.
Mental Health-Residential	This care setting encompasses nearly 10% of Procentive's user base. Including this care setting will demonstrate that the system works in the real world for many of our users.
Substance Use-Outpatient	This care setting encompasses nearly 30% of Procentive's user base. Including this care setting will demonstrate thatthat the sytem works in the real world for many of our users
Substance Use-Residential	This care setting encompasses nearly 20% of Procentive's user base. Including this care setting will demonstrate that the system works in the real world for many of our users.

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

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
b.1 Transitions of Care Over two weeks' time, observe the capture in the audit log of the number of messages with CCDAs attached successfully sent	90% success rate (10% failure accounts for system downtimes, third-party trust issues (e.g., invalid address). Compliant with certification criteria because it is generating a C-CDA version 2.1 consistent with the standards of C-CDA version 2.1. Sending and receiving the C-CDA demonstrates that the system can exchange EHI in all care settings over a two week time frame
b.2 Clinical Information Reconciliation and Incorporation 1) Count number of times reconciliation of medications, allergies and problems is performed over a two-week time frame 2)	Number of times reconciliation is performed for each category. This will demonstrate compliance with certification criteria by the successful reconciliation of problems, medications, and medication allergies from an outside C-CDA version 2.1 within the system as well as display patient's active data and data from outside source simultaneously. It demonstrates interoperability by proving that the system can accept outside EHI and incorporate it. EHI will be received by and used in the certified system. The log will capture that the data within the system was changed based on the incorporation of data.
b.6 Data Export 1) Count the number of times data export is performed over a two-week time frame.	The metrics will demonstrate that the system can successfully generate a C-CDA for individuals, and for multiple clients over two weeks, conforming with C-CDA version 2.1. Conforming to this

	standard will demonstrate the system's interoperability capabilities.
c.1 Record and Export 1) Count of unique customers that have exported at least one QRDA I document in Q1 at all sites.	Generating at least one QRDA at separate sites will demonstrate compliance with certification criteria. The CQM's frequently utilize RX Norm Codes, ICD-10 Codes, SNOMED Codes, and CPT codes to calculate the numerators and denominators. The QRDA's will capture this data and demonstrate the system conforms to the standard value sets.
c.2 Import and Calculate 1) Count number of imported QRDAs which demonstrates successful calculation of CQM's based on imported file	The user will import an outside QRDA to demonstrate successful import and calculation of CQM's. Importing and calculating the QRDA will demonstrate compliance with certification criteria. The CQM's frequently utilize RX Norm Codes, ICD-10 Codes, SNOMED Codes, and CPT codes to calculate the numerators and denominators. The ability to import and then calculate, demonstrates the system's ability to recognize the standard value sets and calculate the measures based on the data received. This also demonstrates the system's interoperability capabilities because it is able to calculate measures based on outside data.
c.3 Report 1) Count number of QRDA are exported with correct CQM calculation	Number of QRDAs demonstrating compliance with certification criteria. The CQM's frequently utilize RX Norm Codes, ICD-10 Codes, SNOMED Codes, and CPT codes to calculate the numerators and denominators. The QRDA's will capture this data and demonstrate the system conforms to the standard value sets.
e.1 VDT 1) Count number of instances a C-CDA is Viewed, downloaded, and transmitted for the user with date and time stamps	Number of instances of separate C-CDAs sent to patient portal and observe the number times the client* views, downloads, and sends/transmits their C-CDA. This demonstrates interoperability as the client can export their data to an outside source.
f.1 Transmission to Immunization Registries 1) Count of user organizations live with this interface. For immunizations, all immunization fields (Start of Vaccine Date, Start of Vaccine Time, Ordering Provider, Administering Provider, Administered Test Code, Administered	Number of customers live with an immunization registry interface. Number of interface transactions. All fields are tracked in the activity log.

Test Code System, Procedure (name of vaccine), Amount, Units, Lot Number, Manufacturer Name, Manufacturer Code, Date Time Expiration, Route, Body Site, Order ID, Substance/treatment Refusal, Administration Notes, and Status) are tracked as "add" in the audit log 2) Count of interface transactions	
f.2 Transmission to Public Health Agencies-Syndromic Surveillance 1) Count of user organizations live with this interface and 90% all observation fields (Date Taken, Observation Type, Observation Value, Coding System, Code, Alt Code, Alt Value, Units Type, Notes, Observation Result, and Status) contain all expected data elements 2) Count of interface transactions	Number of customers live with this interface and 90% of all observation fields contain expected data elements. Number of interface transactions. The ability to capture and modify at least one new observation, including Observation Values demonstrates both compliance with this certification criteria and the vocabulary code sets. It also demonstrates the system's ability to send EHI to an outside source.

*client=patient

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
RWT script writing	Mental Health-Outpatient Mental Health-Residential Substance Use-Outpatient Substance Use-Residential	Apr-Nov 2021
RWT Plan publication to CHPL	Mental Health-Outpatient Mental Health-Residential Substance Use-Outpatient Substance Use-Residential	Dec 2021
RWT – Testing	Mental Health-Outpatient Mental Health-Residential Substance Use-Outpatient	April 2022-June 2022

	Substance Use-Residential	
RWT results aggregation	Mental Health-Outpatient Mental Health-Residential Substance Use-Outpatient Substance Use-Residential	July 2022-Dec 2022
RWT Results publication submission to Drummond	Mental Health-Outpatient Mental Health-Residential Substance Use-Outpatient Substance Use-Residential	January 2023

SVAP

Procentive will not be participating in the Standards Version Advancement Process (SVAP).

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:

Authorized Representative Email:

Authorized Representative Phone:

Authorized Representative Signature:

Date: