REAL WORLD TESTING PLAN

BACKGROUND & INSTRUCTIONS

Under the ONC Health IT Certification Program (**Certification Program**), health IT developers are required to conduct Real World Testing of their certified health IT (45 CFR 170.405). The Office of the National Coordinator for Health Information Technology (ONC) issues Real World Testing resources to clarify health IT developers' responsibilities for conducting Real World Testing, to identify topics and specific elements of Real World Testing that ONC considers a priority, and to assist health IT developers in developing their Real World Testing plans.

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

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

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

- 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program final rule, 85 FR 25642 (May 1, 2020) (**ONC Cures Act Final Rule**)
    - *Section VII.B.5 — "Real World Testing"*

GENERAL INFORMATION

Plan Report ID Number	20231128wel
Developer Name	Welligent, Part of the ContinuumCloud
Product Name(s)	Welligent
Version Number(s)	8MU3
Certified Health IT Product List (CHPL) ID(s)	15.02.05.2536.WELL.01.01.1.220201
Developer Real World Testing Plan Page URL	https://www.welligent.com/solutions/meaningful-health/

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

Overall Expected Outcome(s)

Real World Testing will demonstrate that Welligent' electronic health record (EHR) is conformant to the following certification criteria: § 170.315(b)(1) Transitions of care, § 170.315(b)(2) Clinical information reconciliation and incorporation, § 170.315(g)(7) Application access— patient selection, § 170.315(g)(9) Application access— all data request, § 170.315(g)(10) Standardized API for patient and population services — all data request, and § 170.315(h)(1) Direct Project.

Schedule of Key Milestones

Real World testing starts the first quarter of 2024. Each phase is expected to take the numbers of days listed in the date/timeframe column to complete with a final report to be completed either the end of 2024 or in Q1 of 2025. Timeframes may overlap depending on the milestone.

Key Milestone	Date/Timeframe
Release of documentation for the Real-World Testing to be provided to authorized representatives and providers. This includes surveys, specific instructions on what to look for, how to record issues encountered, and Customer Agreements.	90 days
Collection of information as laid out by the plan for the period.	90 – 180 days
Planned System updates to allow for collection of data after an update.	60 - 90 days
Follow-up with providers and authorized representatives on a regular basis to understand any issues arising with the data collection.	Ongoing
End of Real-World Testing period/final collection of all data for analysis.	90 Days
Analysis, report creation, and submission of Real World Testing report to ACB (per their instructions).	February 1, 2025

Care Coordination & Electronic Exchange

Criteria	Care Setting	Measurement Period
§ 170.315(b)(1) Transitions of care § 170.315(h)(1) Direct Project: from the Electronic Exchange Category	Behavioral Health	Over a 90-day period

Planned Date	Key Milestones
January, 2024	• Begin collection data as laid out in the RWT Plan.
February, 2024	• Confirm Trading Partner • Confirm ability to send and receive clinical documents • Confirm with TP that production data will be used, whether in an actual live environment or a copy of a live environment
Quarterly	• Care provider selects recipient from directory of Direct addresses and initiates sending of Clinical Document. The user is able to create a C-CDA Release 2.1 that also includes the reason for referral, and the referring or transitioning provider's name and office contact information. • C-CDA Care Referral or Referral Note is triggered to send via Direct Protocol • Care provider reviews the Direct Status screen (under Direct Outgoing menu choice) to ensure Clinical Document was successfully transmitted.
Quarterly	Recipient uses scorecard to grade C-CDA
Quarterly	• Tester uses Document Center to locate Clinical Document. • Care provider reviews the Direct Status screen (under Direct Outgoing menu choice). • Recipient validates that Social History section of C-CDA is flagged as restricted
Quarterly	Calculate and compile metrics

Criteria	Care Setting	Measurement Period
§ 170.315(b)(2) Clinical information reconciliation and incorporation	Behavioral Health	Over a 90-day period

Planned Date	Key Milestones
February, 2024	Import live patient data
	Confirm role access limits Verify imported patient data to existing patient match
	Reconcile imported allergy, medication, and problem data with existing data
	Calculate and compile metrics

Application Programming Interfaces

Criteria	Care Setting	Measurement Period
§ 170.315(g)(7) Application access— patient selection § 170.315(g)(9) Application access— all data request	Behavioral Health	Over a 90-day period

Key Milestones
• Partner with PHR or identify existing PHR that can receive patient clinical data as described in this RWT plan. • Ensure that PHR has functionality to access the Dynamic FHIR API, as described here. • Partner with EHR that is integrated with the Dynamic FHIR API and Patient Portal modules of ConnectEHR.
Encounter is created and visually confirmed
• Dynamic FHIR API has transformed C-CDA into FHIR resources. • PHR app consumes FHIR resources to populate EHR data
Visually validate Assessment, Plan of Treatment and Health Concerns narrative text

Criteria	Care Setting	Measurement Period
§ 170.315(g)(10) Standardized API for patient and population services	Behavioral Health	Over a 90-day period

Key Milestones
• Partner with PHR or identify existing PHR that can receive patient clinical data as described in this RWT plan. We recommend MyLinks (https://www.mylinks.com/) • Ensure that PHR has functionality to access the Dynamic FHIR API, as described here. • Partner with EHR that is integrated with the Dynamic FHIR API and Patient Portal modules of ConnectEHR.
• Encounter is created and visually confirmed
• Dynamic FHIR API has transformed C-CDA into FHIR resources. • PHR app consumes FHIR resources to populate EHR data
• Partner with a provider-centric app for improved patient care (e.g. growth charts, clinical decision support, patient charting). • Ensure that app has functionality to access the Dynamic FHIR API, as described here. • Partner with EHR that is integrated with the Dynamic FHIR API module of ConnectEHR.
• Data is rendered correctly: Provider compares patient data in app to patient data in EHR and notes any discrepancies.
• Partner with a provider-centric app that requires periodic bulk data downloads. • Ensure that app has functionality to access the Dynamic FHIR API, as described here. • Partner with EHR that is integrated with the Dynamic FHIR API module of ConnectEHR.
• Data is rendered correctly: Provider compares patient data in app to patient data in EHR and notes any discrepancies.

STANDARDS UPDATES

Standard & Version	USCDI V.1 (170.213)
Updated certification criteria and associated product	b1, b2, g9
Health IT Module CHPL ID	15.02.05.2536.WELL.01.01.1.220201

Date of ONC ACB Notification	12/29/2022
Date notification sent to customers	N/A
Method Used for Standard Update	Cures Update
Conformance Measure	(b)(1) Transition of Care and Direct Project (b)(2) Clinical Information Reconciliation and Incorporation (g)(9) Application Access
USCDI Updated Certification Criteria (and USCDI version)	USCDI v1 – b1, b2, g9

Care Setting	Justification
Outpatient& School Based Behavioral Health including IDD services and residential services (Behavioral Health)	Most of our customer base uses the basic outpatient workflow or identify at least a portion of their business as Behavioral Health.
Primary Care services provided in Behavioral Health Clinics	A small percentage of our customer base provides primary care services operating within a Behavioral Health clinic.

MEASURES USED IN OVERALL APPROACH

Description of Measurement/Metric: Transitions of Care and Direct Project

The following outlines the measures that have been identified to best demonstrate conformance to multiple certification criteria concerning the § 170.315(b)(1) Transition of Care (Cures Update) and § 170.315(h)(1) Direct Project, across two use cases (single patient and population services).

Send and receive Transition of Care (TOC) messages with other providers to close the referral loop. The patient's ePHI will be exchanged using a C-CDA 2.1 Care Referral or Referral Note and DIRECT secure messaging for data transport.

Measurement / Metric	Description	Justification
Outbound TOC's received by HISP	100 percent of outbound TOC's successfully received by HISP	1. Showcase ConnectEHR's streamlined approach to provider-to-provider patient referrals and transitions of care with the goal being higher quality patient care. 2. Reduce risk of manual data entry referral errors by transmitting patient data securely and electronically. 3. Improved efficiency by reducing necessary manual data entry. 4. Ensure private and secure transmission of patients' PHI. 5. Increased interoperability between disparate HIT systems.
C-CDA scorecard	Average C-CDA grade from scorecard for C-CDAs generated from ConnectEHR is a "C" or better	
C-CDA's flagged as restricted received flagged as restricted per the trading partner	75 percent of C-CDAs flagged as restricted were received in restricted status based on confirmed receipt from trading partner	
Trading Partner's TOC C-CDAs received by ConnectEHR	75 percent of trading partner's TOC C-CDAs successfully received by ConnectEHR.	

Associated Certification Criteria

Associated Certification Criteria	Relied Upon Software (if applicable)
§ 170.315(b)(1) Transition of Care (Cures Update)	ConnectEHR
§ 170.315(h)(1) Direct Project	MaxMD

Testing Procedure

Step	Testing Procedure:	Expected Outcomes:
1	Identify Trading Partner (TP) and coordinate with TP for sending/receiving clinical documents using production data as described in this RWT plan.	• Confirm Trading Partner • Confirm ability to send and receive clinical documents • Confirm with TP that production data will be used, whether in an actual live environment or a copy of a live environment
2		• USCDIv1 data elements captured in EHR • Care provider selects Clinical Document to be transmitted. • Care provider is able to create a C- CDA Release 2.1 that also includes the reason for referral, and the referring or transitioning provider's name and office contact information. • Care provider flags the document as restricted and subject to restrictions on re-disclosure.
3	Care provider initiates TOC to TP EHR in EHR	• Care provider selects recipient from directory of Direct addresses and initiates sending of Clinical Document. The user is able to create a C-CDA Release 2.1 that also includes the reason for referral, and the referring or transitioning provider's name and office contact information. • C-CDA Care Referral or Referral Note is triggered to send via Direct Protocol • Care provider reviews the Direct Status screen (under Direct Outgoing menu choice) to ensure Clinical Document was successfully transmitted.
4	Validate that C-CDA for Patient A contains USCDIv1 data elements.	Recipient uses scorecard to grade C- CDA
5	Trading partner refers Patient B from TP EHR to system under test by generating C-CDA Clinical Document or Referral Note.	• Care provider flags Social History section of C-CDA as restricted. • Care provider selects recipient from directory of Direct addresses and initiates sending of Clinical Document. • Tester uses Document Center to locate Clinical Document.
6	In system under test, tester acknowledges receipt of valid Clinical Document.	• Care provider reviews the Direct Status screen (under Direct Outgoing menu choice). • Recipient validates that Social History section of C-CDA is flagged as restricted
7	Calculate and compile metrics	

Description of Measurement/Metric: Clinical Information Reconciliation and Incorporation

Associated Certification Criteria	Relied Upon Software (if applicable)
§ 170.315(b)(2) Clinical information reconciliation and incorporation	ConnectEHR

The following outlines the measures that have been identified to best demonstrate conformance to multiple certification criteria concerning the § 170.315(b)(2) Clinical information reconciliation and incorporation across two use cases (single patient and population services).

Measure Description:
Reconcile and incorporate specific information from C-CDAs formatted to both C-CDA Releases 1.1 and 2.1.

- Demographics for patient matching
- Problems
- Medication
- Allergies

Measures Used

Measurement/ Metric	Description	Justification
Patient Data Matching	100 Percent of patient data can be matched to an existing patient.	1. Demonstrate ability to match received patient data accurately and match to the correct patient 2. Demonstrate the user's ability to reconcile patient medications, allergies, and problem lists to the patient's record
Patient Data Reconciliation	Ability to reconcile data for an existing patient.	

Testing Procedure

Step	Testing Procedure:	Expected Outcomes:	Key Milestone Dates
1	Using production data in an actual live environment or copy of live environment, demonstrate the ability to import medication, allergy, and problem data for a specified client.	•Specified client can be selected through the UL. • Medication, allergy, and problem data is sent through UL.	Begin test: Q4, 2024
2	Demonstrate the ability to limit the set of users who can import data.	Logging in as a User with Admin Profile will allow data to be imported.	
3	Confirm user roles that have been denied import access cannot create import summaries	Logging in as a User with a Non-Admin Profile will not allow access to the export functionality	
4	Verify imported client information matches existing patient in Welligent.	Match the client demographic information to an existing client	
5	Reconcile the medication data imported with medications for the existing patient	Visually verify through a single view which medications match those existing in Welligent for the specific patient and those which do not	
6	Reconcile the allergy data imported with allergy data for the existing patient		

7	Reconcile the problem data imported with problem data for the existing patient		
8	Calculate and compile metrics		Complete test: Q4 2024

Description of Measurement/Metric: Application Access

Associated Certification Criteria	Relied Upon Software (if applicable)
§ 170.315(g)(7) Application access— patient selection	Dynamic FHIR API
§ 170.315(g)(9) Application access— all data request	

Measures Used

The following outlines the measures that have been identified to best demonstrate conformance to multiple certification criteria concerning the § 170.315(g)(7) Application access— patient selection and § 170.315(g)(9) Application access— all data request across two use cases (single patient and population services).

Measure Description:
Enable a patient's access to their electronic health data through a Personal Health Record (PHR) app on their smartphone. They have had a healthcare encounter with a provider using an EHR that is integrated with the Dynamic FHIR API and Patient Portal modules of ConnectEHR. They would like to view the results from that encounter along with the rest of their electronic health record.

Measurement/ Metric	Description	Justification
PHR Access	Patient can retrieve FHIR API data from PHR app for 100 percent of encounters.	Making an electronic copy of the health record available empowers patients to become more involved and knowledgeable of their health care. This allows communication and collaboration with the patient's medical providers leading to improvement in overall population health.
PHR Data Accuracy	In 100 percent of encounters from Step #1, PHR data matches data from EHR. This will be confirmed by visual validation of the following FHIR resources: - Demographics - Problems - Medications - Allergies	

Testing Procedures

Step	Testing Procedure:	Expected Outcomes:
1	Identify Trading Partner (TP) and coordinate with TP for providing patients timely access to their ePHI using production data as described in this RWT plan.	• Partner with PHR or identify existing PHR that can receive patient clinical data as described in this RWT plan. • Ensure that PHR has functionality to access the Dynamic FHIR API, as described here. • Partner with EHR that is integrated with the Dynamic FHIR API and Patient Portal modules of ConnectEHR.
2	Patient A has encounter with care provider who uses EHR described above.	Encounter is created and visually confirmed
3	Provider captures USCDIv1 data elements in EHR	USCDIv1 data elements are validated in the system
4	Provider manually generates Care/Referral Summary C-CDA post-visit or ensures that the EHR generates one automatically.	C-CDA is confirmed for the specified patient
5	Patient A uses Dynamic Patient Portal login to view clinical information	• Patient Portal automatically sends email reminder that Patient A has a new clinical document available. • Email reminder has a URL/hyperlink to the patient portal. • If patient hasn't already activated their portal account, portal account can be activated via Welcome Email or by an Administrator user
6	Patient A uses portal login credentials to log into PHR app	Specific patient ID and token are returned for authentication and data requests Dynamic FHIR API has transformed CCDA into FHIR resources.
7	PHR app displays full set of data for all data categories	• PHR app consumes FHIR resources to populate EHR data
8	PHR app returns full set of data for a given category	PHR app will display and all data to be displayed for each data category
9	PHR app returns data in a computable format using specified standards.	Data is confirmed to be in XML or JSON format
10	PHR app returns full and accurate data for a specific date and specific date range	• Step 10 is optional, if PHR app has the capability to filter by date range • Filtering data by a specific date returns data accurately and as expected • Filtering data by a specific date range returns data accurately and as expected
11	Via visual inspection of PHR app, the data is verified to include Assessment, Plan of Treatment and Health concerns are specified as narrative text	Visually validate Assessment, Plan of Treatment and Health Concerns narrative text
12	Calculate and compile metrics	

Description of Measurement/Metric: Standardized API

Provide a standardized FHIR based API that supports bulk data requests to provide patients, providers, and niche specialty applications to consume patient data enabling improved interoperability improved patient care and better overall population health.

Associated Certification Criteria	Relied Upon Software (if applicable)
§170.315 (g)(10) Standardized API for patient and population services	ConnectEHR +BulkFHIR

Measures Used

The following outlines the measures that have been identified to best demonstrate conformance to multiple certification criteria concerning the § 170.315(g)(10) Standardized API for patient and population services — all data request across two use cases (single patient and population services).

Measurement/ Metric	Description	Justification
PHR Access	Patient can retrieve FHIR API data from PHR app for 100 percent of encounters.	We chose to concentrate on the aspects of this criterion that would empower clinicians with flexibility in choosing new and innovative healthcare technology. Historically, it has been difficult for builders of niche applications to access necessary patient demographic and clinical data for smooth, seamless use of their applications. Likewise, clinicians have often felt forced to stick with cumbersome, difficult-to-use EHR technology because of the cost and complexity of migrating their patient data.
PHR Data Accuracy	In 100 percent of encounters from Step #1, PHR data matches data from EHR. This will be confirmed by visual validation of the following FHIR resources: - Demographics - Problems - Medications - Allergies	

Testing Procedures

Single Patient API Access

Step	Testing Procedure:	Expected Outcomes:
1	Identify Trading Partner (TP) and coordinate with TP for providing patients timely access to their ePHI using production data as described in this RWT plan.	• Partner with PHR or identify existing PHR that can receive patient clinical data as described in this RWT plan. We recommend MyLinks (https://www.mylinks.com/) • Ensure that PHR has functionality to access the Dynamic FHIR API, as described here. • Partner with EHR that is integrated with the Dynamic FHIR API and Patient Portal modules of ConnectEHR.

2	Patient A has encounter with care provider who uses EHR described above.	Encounter is created and visually confirmed
3	Provider captures USCDIv1 data elements in EHR	USCDIv1 data elements are validated in the system
4	Provider manually generates Care/Referral Summary C-CDA post-visit or ensures that the EHR generates one automatically.	C-CDA is confirmed for the specified patient
5	Patient A uses Dynamic Patient Portal login to view clinical information	• Patient Portal automatically sends email reminder that Patient A has a new clinical document available. • Email reminder has a URL/hyperlink to the patient portal. • If patient hasn't already activated their portal account, portal account can be activated via Welcome Email or by an Administrator user
6	Patient A uses portal login credentials to log into PHR app	Specific patient ID and token are returned for authentication and data requests
7	PHR app displays full set of data for each data category	• Dynamic FHIR API has transformed C-CDA into FHIR resources. • PHR app consumes FHIR resources to populate EHR data
8	PHR app returns full set of data for a given category	PHR app will display and all data to be displayed for each data category
9	PHR app returns data in a computable format using specified standards.	Data is confirmed to be in XML or JSON format
10	PHR app returns full and accurate data for a specific date and specific date range	• Step 10 is optional, if PHR app has the capability to filter by date range • Filtering data by a specific date returns data accurately and as expected • Filtering data by a specific date range returns data accurately and as expected
11	Via visual inspection, the data is verified to include Assessment, Plan of Treatment and Health concerns are specified as narrative text	Visually validate Assessment, Plan of Treatment and Health Concerns narrative text

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Care Coordination via 3rd Part App

Step	Testing Procedure	Expected Outcomes:
1a	Identify Trading Partner (TP) and coordinate with TP for providing patients timely access to their ePHI using production data as described in this RWT plan.	• Partner with a provider-centric app for improved patient care (e.g. growth charts, clinical decision support, patient charting). • Ensure that app has functionality to access the Dynamic FHIR API, as described here. • Partner with EHR that is integrated with the Dynamic FHIR API module of ConnectEHR.
2a	Provider logs into app and triggers FHIR API data retrieval	• The app connects to the FHIR API server and pulls down the specific FHIR resources from the EHR
3a	Provider views and validates data in app	• Data is rendered correctly: Provider compares patient data in app to patient data in EHR and notes any discrepancies.

Bulk Data for Care Coordination

Step	Testing Procedure:	Expected Outcomes:
1a	Identify Trading Partner (TP) and coordinate with TP for providing patients timely access to their ePHI using production data as described in this RWT plan.	• Partner with a provider-centric app for improved patient care (e.g. growth charts, clinical decision support, patient charting). • Ensure that app has functionality to access the Dynamic FHIR API, as described here. • Partner with EHR that is integrated with the Dynamic FHIR API module of ConnectEHR.
2a	Provider logs into app and triggers FHIR API data retrieval	• The app connects to the FHIR API server and pulls down the specific FHIR resources from the EHR
3a	Provider views and validates data in app	• Data is rendered correctly: Provider compares patient data in app to patient data in EHR and notes any discrepancies.

For All g(10) Scenarios Above

Step	Testing Procedure:	Expected Outcomes:
12	Calculate and compile metrics	

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	11/20/2023

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

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