REAL WORLD TESTING PLAN 2022

GENERAL INFORMATION

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

Name: Health Catalyst

Product Name(s): Connect Clinical Messaging

Version Number(s): 2.7

Certified Health IT Product List (CHPL) Product Number(s): 15.04.04.3034.Medi.27.01.0.190613

Developer Real World Testing Plan Page URL: https://www.healthcatalyst.com/interoperability-certification/#real-world-testing-plan

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

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

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

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

The Health Catalyst (formerly Medicity) Clinical Connect Messaging product provides secure email exchange via the Direct standard. While it may be utilized in various health care settings, the functionality remains the same across any environment and is marketed to hospital settings. Criteria to be tested: 170.315 (h)(2): Direct Project, Edge Protocol, and XDR/XDM.

STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) AND UNITED STATES CORE DATA FOR INTEROPERABILITY (USCDI))

Both required and voluntary standards updates must be addressed in the Real World Testing plan. Real World Testing plans must include all certified health IT updated to newer versions of standards prior to August 31 of the year in which the updates were made.

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

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

Standard (and version)	N/A
Updated certification criteria and associated product	N/A
CHPL Product Number	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

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

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

Measurement/Metric	Description
Electronic Exchange	The metric used to support this measure is the successful transmission and receipt of simulated patient information via the Direct protocol.

Associated Certification Criteria

List certification criteria associated with the measure and if updated to the 2015 Edition Cures Update criteria. If conformance to the criteria depends on any Relied Upon Software, this should be noted in your Real World Testing plan for any metrics that would involve use of that software in testing.

Measurement/Metric	Associated Certification Criteria	Relied Upon Software (if applicable)
Electronic Exchange	170.315 (h)(2): Direct Project, Edge Protocol, and XDR/XDM	

Justification for Selected Measurement/Metric

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

Measurement/Metric	Justification
Electronic Exchange	The successful transmission and receipt of messages is the desired result of HISP processing for all care settings.

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
Hospital	Health Catalyst HISP clients are typically HIE or enterprise health systems comprised primarily of hospitals. Since a hospital represents the type of care setting where the HISP product is ultimately used, that is where testing will take place.

Expected Outcomes

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

1) is compliant with the certification criteria, including the required technical standards and vocabulary codes sets;
2) is exchanging electronic health information (EHI) in the care and practice settings for which it is marketed for use; and/or,
3) EHI is received by and used in the certified health IT.

(from 85 FR 25766)

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

Within this section, health IT developers should also describe how the specific data collected from their Real World Testing measures demonstrate expected results. Expected outcomes and specific measures

do not necessarily have to include performance targets or benchmarks, but health IT developers should provide context for why specific measures were selected and how the metrics demonstrate individual criterion functionality, EHI exchange, and/or use of EHI within certified health IT, as appropriate.

Measurement/Metric	Expected Outcomes
Successful transmission of EHI via two messages	Two secure emails will be sent to the recipient endpoint. One message will have an attachment and one will not. The desired outcome will be that two messages will be successfully transmitted, and the appropriate Direct responses will be received and captured for reporting purposes to show that the application is compliant with 170.315 (h)(2).
Successful receipt of two EHI messages	Two secure emails will be received and processed by the recipient partner in testing. We will capture the Direct Message replies to both messages. The anticipated outcome is that the data received will be identical to the data transmitted in the original message and that the application is compliant with 170.315 (h)(2).

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
Submit RWT plan to Drummond	Hospital	11/15/2022
Identify Real World Testing Partner	Hospital	Q1/2023
Key Milestone	**Care Setting**	**Date/Timeframe**
Perform Real World Testing	Hospital	Q2-Q3/2023
Submit 2023 RWT plan to Drummond	Hospital	11/15/2023
Analysis and report creation for 2022 testing	**Hospital**	**1/15/2024**

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: William Frazier

Authorized Representative Email: wc.frazier@healthcatalyst.com

Authorized Representative Phone: 770-797-8158

Authorized Representative Signature: 

Date:

10/19/2022

[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

REAL WORLD TESTING RESULTS 2022

GENERAL INFORMATION

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

Developer Name: Health Catalyst

Product Name(s): Medicity Connect Clinical Messaging

Version Number(s): 2.7

Certified Health IT Product List (CHPL) Product Number(s): 15.04.04.3034.Medi.27.01.0.190613

Developer Real World Testing Plan Page URL: https://www.healthcatalyst.com/interoperability-certification/#real-world-testing-plan

Developer Real World Testing Results Report Page URL [if different from above]:

[OPTIONAL] CHANGES TO ORIGINAL PLAN

If a developer has made any changes to their approach for Real World Testing that differs from what was outlined in their plan, note these changes here.

Summary of Change [Summarize each element that changed between the plan and actual execution of Real World Testing]	**Reason** [Describe the reason this change occurred]	**Impact** [Describe what impact this change had on the execution of your Real World Testing activities]

[OPTIONAL] WITHDRAWN PRODUCTS

If a developer withdrew any products within the past year that were previously included in their Real World Testing plan, please provide the following information.

Product Name(s):	
Version Number(s):	

CHPL Product Number(s):	
Date(s) Withdrawn:	
Inclusion of Data in Results Report: [Provide a statement as to whether any data was captured on the withdrawn products. If so, this data should be identified in the results report.]	

SUMMARY OF TESTING METHODS AND KEY FINDINGS

Provide a summary of the Real World Testing methods deployed to demonstrate real-world interoperability, including any challenges or lessons learned from the chosen approach. Summarize how the results that will be shared in this report demonstrate real-world interoperability.

If any non-conformities were discovered and reported to the ONC-ACB during testing, outline these incidences and how they were addressed.

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

The Connect Clinical Messaging product is Health Catalyst's Direct Secure Messaging solution. The Real World Test Plan included the sending and receiving of Direct Secure Messages with and without an attachment.

The expected results were that the messages would be successfully received and processed by both parties and that the attachment would be readable.

Four Direct Secure Messages were exchanged with a hospital client. Two included attachments and two did not. All were successfully exchanged and readable.

STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) AND UNITED STATES CORE DATA FOR INTEROPERABILITY (USCDI))

Both required and voluntary standards updates must be addressed in the Real World Testing plan. Real World Testing plans must include all certified health IT updated to newer versions of standards prior to August 31 of the year in which the updates were made.

Indicate as to whether optional standards, via SVAP and/or USCDI, are leveraged as part of the certification of your health IT product(s).

[ ] Yes, I have products certified with voluntary SVAP or USCDI standards. (If yes, please complete the table below.

[X] No, none of my products include these voluntary standards.

Standard (and version)	
Updated certification criteria and associated product	
CHPL Product Number	
Conformance measure	

Care Setting(s)

The expectation is that a developer's Real World Testing is conducted within 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.

List each care setting that was tested.

Health Catalyst HISP clients are typically HIE or enterprise health systems comprised primarily of hospitals. Since a hospital represents the type of care setting where the HISP product is ultimately used, that is where testing took place.

Metrics and Outcomes

Health IT developers should detail outcomes from their testing that successfully demonstrate that the certified health IT:

1. is compliant with the certification criteria, including the required technical standards and vocabulary codes sets;
2. is exchanging electronic health information (EHI) in the care and practice settings for which it is marketed for use; and/or,
3. EHI is received by and used in the certified health IT.

(from 85 FR 25766)

Health IT developers could also detail outcomes that did 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 their results. Where possible, context should be provided to the measures and results to understand the number of sites/users/transactions tested for the specified measures (i.e., the denominator for comparison to the reported results). If applicable, any Relied Upon Software that is used to meet a criterion's requirements should be included in this section.

Measurement /Metric	Associated Criterion(a)	Relied Upon Software (if applicable)	Outcomes	Challenges Encountered (if applicable)
Electronic Exchange	170.315 (h)(2): Direct Project, Edge Protocol, and XDR/XDM		Four Direct Messages were successfully transmitted and received. Messages were readable along with any attachment.	

KEY MILESTONES

Include a list of key milestones that were met during the Real World Testing process. Include details on how and when the developer implemented measures and collected data. Key milestones should be relevant and directly related to outcomes discussed.

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

Key Milestone	Care Setting	Date/Timeframe
Four Direct Secure Messages were successfully exchanged in the production environment. Two had attachments and two did not.	Hospital	10/10/2022