



REAL WORLD TESTING PLAN TEMPLATE

BACKGROUND & INSTRUCTIONS

Under the ONC Health IT Certification Program (**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 – Coming Soon
- [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 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”

TEMPLATE INSTRUCTIONS

The following template is organized by elements required to be submitted in the Real World Testing plan. Each section provides a field for submitting responses and/or explanations for how the health IT developer will address each required element in their Real World Testing approach. These fields serve as a foundation of information

required for developing a Real World Testing plan and can be expanded with additional rows or columns to address the specific needs of the Real World Testing plan being submitted.

GENERAL INFORMATION

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

Developer Name: Orion Health

Product Name(s): Communicate

Version Number(s): 2.4

Certified Health IT: ONC Certified Health IT 2015

Product List (CHPL) ID(s): 15.04.04.2113.Comm.23.01.0.210305

Developer Real World Testing Page URL: pending, will be available on orionhealth.com website under <https://orionhealth.com/us/support/disclosures/onc-hit-certification-communicate/>

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 Testing¹.

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.

Testing will cover the accreditation required interfaces along with data and payload standards conformity. This will demonstrate support for all required Edge Interfaces, compliance with message success and failure scenarios according to Direct Trust standards as well as correct handling of all cryptographic requirements. We will demonstrate this support in our live Production environment using a combination of client sent messages as well as internal testing when clients are not able to create adequate positive or negative test scenarios.

Testing will also demonstrate capability to successfully exchange data with other accredited HISPs.

This allows us to demonstrate support for compliant systems using our HISP solution, as well as correct handling for any non-compliant systems, in a secure manner which allows the exchange of data to be performed with other participants and HISPs. It also covers all Care Settings currently using the Orion Health Communicate solution.

¹ 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)



Health IT Certification Program

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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 ID 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)	ONC Health IT 2015 Edition
Updated certification criteria and associated product	170.315 (h)(2): Direct Project, Edge Protocol, and XDR/XDM Orion Health Ltd. Communicate
Health IT Module CHPL ID	15.04.04.2113.Comm.23.01.0.210305
Method used for standard update	N/A
Date of ONC-ACB notification	Mar 5, 2021
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
Send	Ability for a client to successfully send a Direct message to an intended recipient.
Receive	Ability for a client to receive a Direct message as the intended recipient.
Send using Direct + XDM	Extends "Send" to include messages with XDM payloads.
Send conversion using XDR	Extends "Send" for use of the Direct XDR edge interface.
Receive using Direct + XDM	Extends "Receive" to includes messages with XDM payloads.
Receive conversion using XDR	Extends "Receive" for use of the Direct XDR edge interface.
Send Using Edge Protocol for IHE XDR profile for Limited Metadata Document Sources	Extends "Send conversion using XDR" with positive and negative test scenarios as well as various payload metadata scenarios.
Send Using Edge Protocol for SMTP	Extends "Send" for use of a third-party mail client via a secure, authenticated SMTP interface.
Send Using Edge Protocol for IMAP (SMTP Alternative)	Extends "Send" for use of a third-party mail client via a secure, authenticated IMAP interface.
Receive Using Edge Protocol for IHE XDR profile for Limited Metadata Document Sources	Extends "Receive conversion using XDR" to demonstrate security compliance with forming the mutual TLS connection as well as correct handling of invalid XDR payloads.
Receive Using Edge Protocol for SMTP	Extends "Receive" to include receiving via a SASL authenticated SMTP edge interface.
Send (Acknowledgements)	Client is informed of the success or failure status of a sent Direct message.
Receive (Acknowledgements)	Client is informed of the success or failure status of a sent Direct message.
Send (Enhanced Testing – v1.2)	Client is able to send Direct messages to other participants of the Direct Trust network who are not members of the Orion Health HISP.
Receive (Enhanced Testing – v1.2)	Client is able to receive Direct messages from other participants of the Direct Trust network who are not members of the Orion Health HISP.
Send (Enhanced Testing – XDR and XDM)	Extends "Send (Enhanced Testing – v1.2)" to include Direct with XDM messages of various metadata level payloads.
Receive (Enhanced Testing – XDR and XDM)	Extends "Receive (Enhanced Testing – v1.2)" to include Direct with XDM messages of various metadata level payloads.

ASSOCIATED CERTIFICATION CRITERIA

List certification criteria associated with the measure and if updated to the 2015 Edition Cures Update criteria.

Measurement/Metric	Associated Certification Criteria
Send	Paragraph (h)(2)(i)(A) – Send
Receive	Paragraph (h)(2)(i)(A) – Receive
Send using Direct + XDM	Paragraph (h)(2)(i)(B) – Send using Direct + XDM
Send conversion using XDR	Paragraph (h)(2)(i)(B) – Send conversion using XDR
Receive using Direct + XDM	Paragraph (h)(2)(i)(B) – Receive using Direct + XDM
Receive conversion using XDR	Paragraph (h)(2)(i)(B) – Receive conversion using XDR
Send Using Edge Protocol for IHE XDR profile for Limited Metadata Document Sources	Paragraph (h)(2)(i)(C) – Send Using Edge Protocol for IHE XDR profile for Limited Metadata Document Sources
Send Using Edge Protocol for SMTP	Paragraph (h)(2)(i)(C) – Send Using Edge Protocol for SMTP
Send Using Edge Protocol for IMAP (SMTP Alternative)	Paragraph (h)(2)(i)(C) – Send Using Edge Protocol for IMAP (SMTP Alternative)
Receive Using Edge Protocol for IHE XDR profile for Limited Metadata Document Sources	Paragraph (h)(2)(i)(C) – Receive Using Edge Protocol for IHE XDR profile for Limited Metadata Document Sources
Receive Using Edge Protocol for SMTP	Paragraph (h)(2)(i)(C) – Receive Using Edge Protocol for SMTP
Send (Acknowledgements)	Paragraph (h)(2)(ii) – Send
Receive (Acknowledgements)	Paragraph (h)(2)(ii) – Receive
Send (Enhanced Testing – v1.2)	Paragraph (h)(2)(i)(A) – Send
Receive (Enhanced Testing – v1.2)	Paragraph (h)(2)(i)(A) – Required Enhanced Testing, Receive
Send (Enhanced Testing – XDR and XDM)	Paragraph (h)(2)(i)(B) – Send
Receive (Enhanced Testing – XDR and XDM)	Paragraph (h)(2)(i)(B) – Required Enhanced Testing, Receive

JUSTIFICATION FOR SELECTED MEASUREMENT/METRIC

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

Measurement/Metric	Justification
Send	Demonstrates the ability to secure the message for transport using Direct Certificates as described by the Direct Trust standard.

Receive	Demonstrates the ability to receive and decrypt a message which has been signed and encrypted for Direct delivery. Includes coverage of failure scenarios related to the encryption method used by the sending party.
Send using Direct + XDM	Confirms sending scenario when an XDM payload is present in the message.
Send conversion using XDR	Confirms sending scenario when sending via a Direct XDR interface and the implicit conversion to an XDM payload for the Direct message. Demonstrates the ability to convert a Direct with XDM payload message into a compliant Direct XDR document and create a secure mutual TLS connection to deliver the resulting document.
Receive using Direct + XDM	Confirms receiving scenario when an XDM payload is present in the message.
Receive conversion using XDR	Demonstrates the ability to receive a compliant Direct XDR document over a secure mutual TLS connection and convert to a Direct and XDM payload message for delivery.
Send Using Edge Protocol for IHE XDR profile for Limited Metadata Document Sources	Extends “Send conversion using XDR” with positive and negative test scenarios as well as various payload metadata scenarios.
Send Using Edge Protocol for SMTP	Demonstrates the ability to use a TLS secured SMTP interface to send Direct messages as well as various positive and negative scenarios with correct error handling leading to informative user feedback via message disposition notifications.
Send Using Edge Protocol for IMAP (SMTP Alternative)	Demonstrates the ability to use a TLS secured IMAP interface to access received Direct messages as well as various positive and negative scenarios showing a secured interface.
Receive Using Edge Protocol for IHE XDR profile for Limited Metadata Document Sources	Extends “Receive conversion using XDR” to demonstrate security compliance with forming the mutual TLS connection as well as correct handling of invalid XDR payloads.
Receive Using Edge Protocol for SMTP	Extends “Send Using Edge Protocol for SMTP” to include receiving via a SASL authenticated SMTP edge interface with positive and negative test scenarios.
Send (Acknowledgements)	Demonstrates the ability to respond to positive and negative scenarios around message disposition notifications in accordance with the Direct Trust standard when acting as the sending HISP.
Receive (Acknowledgements)	Demonstrates the ability to respond to positive and negative scenarios around message disposition notifications in accordance with the Direct Trust standard when acting as the receiving HISP.
Send (Enhanced Testing – v1.2)	Extends “Send” scenario to demonstrate interoperability when acting as the sending HISP and sending to other partner HISPs.
Receive (Enhanced Testing – v1.2)	Extends “Receive” scenario to demonstrate interoperability when acting as the receiving HISP and receiving from other partner HISPs.
Send (Enhanced Testing – XDR and XDM)	Extends “Send (Enhanced Testing – v1.2)” to include Direct with XDM messages of various metadata level payloads.
Receive (Enhanced Testing – XDR and XDM)	Extends “Receive (Enhanced Testing – v1.2)” to include Direct with XDM messages of various metadata level payloads.

CARE SETTING(S)



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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
Site with XDR compliant EHR system, e.g. a Hospital	Included as a demonstration of Orion Health Communicate's support for the Direct XDR interface. XDR sites are representative of a large portion of the total Direct traffic that we service. This will cover scenarios of submitting system messages as payloads for HIE data ingestion purposes as well as delivering patient data for human user consumption.
Site using Webmail or other mail client solution, e.g. a General Practice site	Demonstrates use sending and receiving scenarios through either use of the dedicated web client (Webmail) or use a user selected third-party mail client (e.g. Outlook). This will cover scenarios of user sending and receiving and non-system based edge interface usage.

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
Send	<p><i>Client will be engaged to perform standard Direct messaging sending scenario and provide feedback on the outcome in coordination with observation of the receiving parties receipt of the send message.</i></p> <p><i>Success and error rates are measured through logs, auditing, audit based reports that are provided to clients as well as real-time feedback to client users/systems. Monitoring is also in place around potential places of failure for alerting.</i></p>
Receive	<p><i>Receiving party of the “Send” measurement will be observed for successful receipt of the send message.</i></p> <p><i>Success and error rates are measured through logs, auditing, audit based reports that are provided to clients as well as real-time feedback to client users/systems. Monitoring is also in place around potential places of failure for alerting.</i></p>
Send using Direct + XDM	<p><i>Client will be engaged to perform Direct messaging sending using an XDM attachment and provide feedback on the outcome in coordination with observation of the receiving parties receipt of the send message.</i></p> <p><i>Success and error rates are measured through logs, auditing, audit based reports that are provided to clients as well as real-time feedback to client users/systems. Monitoring is also in place around potential places of failure for alerting.</i></p>
Send conversion using XDR	<p><i>A Direct XDR client will be engaged to perform Direct messaging sending using a Direct XDR document to a non-Direct XDR client and provide feedback on the outcome in coordination with observation of the receiving parties receipt of the send message.</i></p> <p><i>Success and error rates are measured through logs, auditing, audit based reports that are provided to clients as well as real-time feedback to client users/systems. Monitoring is also in place around potential places of failure for alerting.</i></p>
Receive using Direct + XDM	<p><i>Receiving party of the “Send conversion using XDR” measurement will be observed for successful receipt of the send message.</i></p> <p><i>Success and error rates are measured through logs, auditing, audit based reports that are provided to clients as well as real-time feedback to client users/systems. Monitoring is also in place around potential places of failure for alerting.</i></p>
Receive conversion using XDR	<p><i>Receiving party of the “Send using Direct + XDM” measurement will be observed for successful receipt of the send message as well as validation of the correct payload.</i></p>



	<p><i>Success and error rates are measured through logs, auditing, audit based reports that are provided to clients as well as real-time feedback to client users/systems. Monitoring is also in place around potential places of failure for alerting.</i></p>
Send Using Edge Protocol for IHE XDR profile for Limited Metadata Document Sources	<p><i>Extends "Send conversion using XDR" with various metadata profiles. Negative test scenarios will be performed internally.</i></p> <p><i>Success and error rates are measured through logs, auditing, audit based reports that are provided to clients as well as real-time feedback to client users/systems. Monitoring is also in place around potential places of failure for alerting.</i></p>
Send Using Edge Protocol for SMTP	<p><i>Client will be engaged to send a Direct message using their choice of third-party mail client.</i></p> <p><i>Success and error rates are measured through logs, auditing, audit based reports that are provided to clients as well as real-time feedback to client users/systems. Monitoring is also in place around potential places of failure for alerting.</i></p>
Send Using Edge Protocol for IMAP (SMTP Alternative)	<p><i>Client will be engaged to access a Direct message using their choice of third-party mail client.</i></p> <p><i>Success and error rates are measured through logs, auditing, audit based reports that are provided to clients as well as real-time feedback to client users/systems. Monitoring is also in place around potential places of failure for alerting.</i></p>
Receive Using Edge Protocol for IHE XDR profile for Limited Metadata Document Sources	<p><i>Extends "Receive conversion using XDR" to include scenarios tested under "Send Using Edge Protocol for IHE XDR profile for Limited Metadata Document Sources". Negative scenarios will be confirmed internally.</i></p> <p><i>Success and error rates are measured through logs, auditing, audit based reports that are provided to clients as well as real-time feedback to client users/systems. Monitoring is also in place around potential places of failure for alerting.</i></p>
Receive Using Edge Protocol for SMTP	<p><i>We will internally validate the ability to receive via an authenticated SMTP endpoint.</i></p> <p><i>Success and error rates are measured through logs, auditing, audit based reports that are provided to clients as well as real-time feedback to client users/systems. Monitoring is also in place around potential places of failure for alerting.</i></p>
Send (Acknowledgements)	<p><i>Positive scenarios will be tested via clients and partnered external HISPs, negative scenarios will be tested internally or through use of the ETT tool to simulate failing external HISP scenarios.</i></p> <p><i>Success and error rates are measured through logs, auditing, audit based reports that are provided to clients as well as real-time feedback to client users/systems. Monitoring is also in place around potential places of failure for alerting.</i></p>

Receive (Acknowledgements)	<p><i>Positive scenarios will be tested via clients and partnered external HISPs, negative scenarios will be tested internally or through use of the ETT tool to simulate failing external HISP scenarios.</i></p> <p><i>Success and error rates are measured through logs, auditing, audit based reports that are provided to clients as well as real-time feedback to client users/systems. Monitoring is also in place around potential places of failure for alerting.</i></p>
Send (Enhanced Testing – v1.2)	<p><i>Positive scenarios will be tested via clients and partnered external HISPs, negative scenarios will be tested internally or through use of the ETT tool to simulate failing external HISP scenarios.</i></p> <p><i>Success and error rates are measured through logs, auditing, audit based reports that are provided to clients as well as real-time feedback to client users/systems. Monitoring is also in place around potential places of failure for alerting.</i></p>
Receive (Enhanced Testing – v1.2)	<p><i>Positive scenarios will be tested via clients and partnered external HISPs, negative scenarios will be tested internally or through use of the ETT tool to simulate failing external HISP scenarios.</i></p> <p><i>Success and error rates are measured through logs, auditing, audit based reports that are provided to clients as well as real-time feedback to client users/systems. Monitoring is also in place around potential places of failure for alerting.</i></p>
Send (Enhanced Testing – XDR and XDM)	<p><i>Positive scenarios will be tested via clients and partnered external HISPs, negative scenarios will be tested internally or through use of the ETT tool to simulate failing external HISP scenarios.</i></p> <p><i>Success and error rates are measured through logs, auditing, audit based reports that are provided to clients as well as real-time feedback to client users/systems. Monitoring is also in place around potential places of failure for alerting.</i></p>
Receive (Enhanced Testing – XDR and XDM)	<p><i>Positive scenarios will be tested via clients and partnered external HISPs, negative scenarios will be tested internally or through use of the ETT tool to simulate failing external HISP scenarios.</i></p> <p><i>Success and error rates are measured through logs, auditing, audit based reports that are provided to clients as well as real-time feedback to client users/systems. Monitoring is also in place around potential places of failure for alerting.</i></p>

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
Recruit clients to take part in Real World Testing plan.	All Care Settings.	Completed by April 31 st , 2024.
Recruit partner HISPs to take part in Real World Testing plan.	N/A	Completed by May 30 th , 2024.
Conduct testing.	All Care Settings.	Completed by August 31 st , 2024.
Secondary testing period in case of issues or conflicts with clients and partner HISPs.	All Care Settings.	Completed by November 30 th , 2024.
Collation and finalization of results.	N/A	Completed by February 1 st , 2025.

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.²

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: JAMES RICE

Authorized Representative Email: james.rice@orionhealth.com

Authorized Representative Phone:

Authorized Representative Signature:

Date: 11 Oct 2023



² <https://www.federalregister.gov/d/2020-07419/p-3582>