



Real World Testing Plan

§170.315(h)(2) Direct Project, Edge Protocol, and XDR/XDM

Nov 17, 2021

Version 1.1

Copyright © 2021, DataMotion, Inc. ("DataMotion"). ALL RIGHTS RESERVED.

Your right to print, copy, reproduce, publish or distribute this document or parts of this document is limited by copyright law.

DataMotion® is a registered trademark of DataMotion, Inc. All other brand and product names are trademarks or registered trademarks of their respective companies.

The information contained in this document is subject to change without notice. THIS DOCUMENT IS PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND. IN NO EVENT SHALL DATAMOTION BE LIABLE FOR INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES OF ANY KIND ARISING FROM ANY ERROR IN THIS DOCUMENT, INCLUDING WITHOUT LIMITATION ANY LOSS OR INTERRUPTION OF BUSINESS, PROFITS, USE, OR DATA.

DataMotion, Inc.
67 East Park Pl. suite 301
Morristown, NJ 07960
USA

<http://www.datamotion.com/>

Table of Contents

1 Introduction 4

2 Real World Testing Plan 5

2.1 Developer information 5

2.2 Approach for demonstrating conformance to certification requirements for the §170.315(h)(2) Direct Project, Edge Protocol, and XDR/XDM criterion 5

2.2.1 Justification of the approach 6

2.3 Standards updates 6

2.4 Measures used in overall approach 7

2.4.1 XDR Send Tests: 170.315(h)(2)(i)(C) Send Using Edge Protocol for IHE XDR profile for Limited Metadata 7

2.4.1.1 Justification for measurement/metric..... 7

2.4.2 XDR Receive Tests: 170.315(h)(2)(i)(C) Receive Using Edge Protocol for IHE XDR profile for Limited Metadata: from Tampa to another HISP 7

2.4.2.1 Justification for measurement/metric..... 7

2.4.3 Failure use cases 7

2.4.3.1 Validate that customer’s XDR endpoint does not connect to a system with an invalid/untrusted SSL certificate..... 7

2.4.3.2 Validate Trust for Direct Address being sent to..... 8

2.4.3.3 Validate Mutual TLS on our Sandbox XDR endpoint. 8

2.4.3.4 Justification for measurement/metric..... 8

2.4.4 SMTP Send Tests: 170.315(h)(2)(i)(C) Send Using Edge Protocol for SMTP 8

2.4.4.1 Validate that DataMotion SMTP endpoint requires a TLS connection before sending any messages to a client SMTP endpoint. 8

2.4.4.2 Validate the content of the document sent over SMTP edge protocol. 8

2.4.5 SMTP Receive Tests: 170.315(h)(2)(i)(C) Receive Using Edge Protocol for SMTP 8

2.4.5.1 Validate DataMotion Sandbox SMTP endpoint enforces STARTTLS and requires credentials before receiving any messages. 8

2.4.5.2 Validate the DataMotion Sandbox SMTP endpoint can receive messages to be sent via Direct. 9

2.5 Care setting 9

2.6 Expected outcomes 9

2.7 Schedule & key milestones 9

3 Attestation 11

1 Introduction

[Real World Testing \(RWT\)](#) is a process by which Certified Health IT Developers demonstrate interoperability and functionality of their certified health IT in real world settings and scenarios, rather than in a controlled test environment. Starting December 2021 and on, RWT is a condition of Certification for Health IT Developers with one or more Health IT Module(s) certified to any of the certification criteria outlined in §170.405(a) of the ONC Cures Act Final Rule.

Because DataMotion is certified to the criterion [§170.315\(h\)\(2\) Direct Project, Edge Protocol, and XDR/XDM](#) included in this list, DataMotion is required to develop and conduct RWT in 2022.

This document includes the RWT Plan developed by DataMotion to address this requirement, including the following aspects:

1. Developer information
2. Approach for demonstrating conformance to certification requirements for the [§170.315\(h\)\(2\) Direct Project, Edge Protocol, and XDR/XDM](#) criterion and its justification.
3. Standards updates, including standards version advancement process (SVAP) and United States Core Data for Interoperability (USCDI).
4. Measures used in overall approach and their justification
5. Care setting(s)
6. Expected outcomes
7. Schedule & key milestones

2 Real World Testing Plan

2.1 Developer information

Plan Report ID Number: [To be assigned, for ONC-Authorized Certification Body use only]

Developer Name: DataMotion, Inc.

Product Name(s): DataMotion Direct

Version Number(s): 6.4

Certified Health IT: 1327

Product List (CHPL) ID(s): 15.04.04.1327.Data.64.01.0.190509

Developer Real World Testing Page URL: <https://datamotion.com/healthcare-solutions-certifiedhit/>

2.2 Approach for demonstrating conformance to certification requirements for the §170.315(h)(2) Direct Project, Edge Protocol, and XDR/XDM criterion

As a HISP, DataMotion is required to certify for the §170.315(h)(2) criterion such that all HIT developers who use DataMotion HISP services can use DataMotion HISP as relied-upon software in their certifications (primarily, for the §170.315 (b)(1) criterion) and in real world deployments. All DataMotion customers who use Edge protocols to connect to Direct via DataMotion HISP are hospitals and affiliated healthcare organizations who use clinical EMRs (EPIC and Meditech). All of them connect to DataMotion HISP via the XDR protocol. All other DataMotion customers use DataMotion APIs and Direct Web portal to connect to DataMotion HISP. DataMotion currently has no customers who use SMTP as an edge protocol for connecting to Direct via DataMotion HISP. Being a HISP, DataMotion does not have access to any content of the payloads of messages and attachments sent over Direct using its services.

The approach taken in this is to measure the metrics that indicate:

- (1) Successful (a) transmission of messages received from clinical EMRs over XDR to Direct to intended Direct recipients, and (b) receipt of correct Direct delivery confirmations from intended recipients.
- (2) Successful (a) transmission of messages received over Direct to clinical EMRs over XDR and (b) receipt of correct XDR delivery confirmations from intended recipients.
- (3) The same 2 scenarios when using SMTP as an edge protocol, contingent on the availability of customers who use SMTP an edge protocol for connecting to Direct (there are currently no such

customers). In case if they do not become available, testing shall be performed in simulated environment.

All of the above testing will be performed on the DataMotion sandbox HISP, which is connected to the [Direct Trust Interoperability Testing Bundle](#) that allows exchanges with all other participants of that bundle. We will partner with DataMotion customers to perform these tests with their Test system through DataMotion Sandbox system for Direct.

2.2.1 Justification of the approach

Using the approach outlined above, DataMotion will demonstrate the successful implementation of bidirectional exchange of messages with attached Electronic Health Records (EHI) over Direct protocol for clinical EMRs who use XDR as an edge protocol to connect to Direct via DataMotion HISP. Implementing such bidirectional exchange with Direct senders and recipients on other HISPs will demonstrate real-world interoperability as key objective of the certification for §170.315(h)(2) criterion.

2.3 Standards updates

Standard (and version)

Updated certification criteria and associated product	<p>Direct Project: ONC Applicability Statement for Secure Health Transport, Version 1.2, August 2015</p> <p>Paragraph (h)(2)(i)(B): § 170.202(b) ONC XDR and XDM for Direct Messaging Specification, March 2011</p> <p>Paragraph (h)(2)(i)(C): § 170.202(d) ONC Implementation Guide for Direct Edge Protocols, Version 1.1, June 25, 2014</p> <p>Paragraph (h)(2)(ii): § 170.202(e)(1) Delivery Notification - Implementation Guide for Delivery Notification in Direct v1.0</p>
Health IT Module CHPL ID	15.04.04.1327.Data.64.01.0.190509
Method used for standard update	SVAP (if and when new versions are available)
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
--	-----

2.4 Measures used in overall approach

2.4.1 XDR Send Tests: 170.315(h)(2)(i)(C) Send Using Edge Protocol for IHE XDR profile for Limited Metadata

Send test messages with XML or XDM-formatted test attachments (no PHI) over Direct from other HISP(s) on the Direct Interoperability Testing Bundle to DataMotion customer’s Sandbox XDR endpoint(s). Validate that all messages are received and ingested properly. In addition to the other HISPs, messages can be sent from the DataMotion test Direct portal that would simulate other HISPs. Measured by collecting and processing the logs that indicate delivery status.

2.4.1.1 Justification for measurement/metric

This metric shows the actual success rate of delivering messages and attachments over XDR to Direct and receipt of delivery notifications.

2.4.2 XDR Receive Tests: 170.315(h)(2)(i)(C) Receive Using Edge Protocol for IHE XDR profile for Limited Metadata: from Tampa to another HISP

Send test messages with XML documents (no PHI) from DataMotion customer’s Sandbox XDR endpoint to DataMotion Sandbox XDR endpoint and validate the document is received, converted to an XDM properly and delivered by DataMotion HISP to the destination Direct address (which can be on another HISP connected to the Direct Interoperability Testing Bundle or on DataMotion Sandbox HISP). Message can be downloaded/inspected by the receiving HISP or DataMotion Sandbox HISP portal. Further, for each message validate that a DSN is sent back to and processed by the customer’s Sandbox XDR endpoint. Measured by collecting and processing the logs that indicate delivery status.

2.4.2.1 Justification for measurement/metric

This metric shows the actual success rate of delivering messages and attachments from Direct over XDR to and receipt of delivery notifications.

2.4.3 Failure use cases

2.4.3.1 Validate that customer’s XDR endpoint does not connect to a system with an invalid/untrusted SSL certificate.

Remove the customer’s XDR sandbox endpoint’s certificate from the trust store of the DataMotion XDR endpoint and attempt to connect to the customer’s sandbox XDR endpoint. Measured by collecting and processing the logs that indicate connection status. This use case can only be tested in a controlled experiment.

2.4.3.2 Validate Trust for Direct Address being sent to.

Customer attempts to send a message from their XDR system to an untrusted/non-existent Direct address. Verify the system responds with a failure indicating address is not trusted. Measured by collecting and processing the logs that indicate connection status. This use case can be tested in a controlled experiment and in real-world cases when a message is attempted to be sent to an invalid Direct address.

2.4.3.3 Validate Mutual TLS on our Sandbox XDR endpoint.

Remove the client's Auth cert from DataMotion Sandbox XDR endpoint. Verify that customer cannot establish a secure connection to DataMotion Sandbox XDR endpoint. Measured by collecting and processing the logs that indicate connection status. This use case can only be tested in a controlled experiment.

2.4.3.4 Justification for measurement/metric

Metrics in this category reflect that all security-related measures must be in place in order for bi-directional exchange of messages and attachments over Direct using XDR as edge protocol to take place.

2.4.4 SMTP Send Tests: 170.315(h)(2)(i)(C) Send Using Edge Protocol for SMTP

Since DataMotion does not have any SMTP customers, these tests will be done in a controlled environment.

2.4.4.1 Validate that DataMotion SMTP endpoint requires a TLS connection before sending any messages to a client SMTP endpoint.

Configure a SMTP test server to require TLS on inbound connections or not use TLS at all. Verify that the DataMotion Direct Sandbox SMTP endpoint rejects the connection and does not allow message to be sent without TLS enabled. Measured by collecting and processing the logs that indicate connection status.

2.4.4.2 Validate the content of the document sent over SMTP edge protocol.

Send a message from DataMotion Sandbox SMTP endpoint to a test SMTP server. Measured by manually downloading the document from the SMTP test server and comparing to the document sent.

2.4.5 SMTP Receive Tests: 170.315(h)(2)(i)(C) Receive Using Edge Protocol for SMTP

Since DataMotion does not have any SMTP customers, these tests will be done in a controlled environment.

2.4.5.1 Validate DataMotion Sandbox SMTP endpoint enforces STARTTLS and requires credentials before receiving any messages.

Using SMTP test server configured with a relay route and setup to log into the SMTP endpoint with credentials, verify the Sandbox system enforces STARTTLS as well as PLAIN SASL authentication for

inbound SMTP clients. SMTP test server x can be configured to require a TLS connection by setting smtp_tls_security_level = encrypt.

1. By setting smtp_tls_security_level = none, validate the Sandbox SMTP endpoint rejects the connection before a message is sent if TLS is not requested.
2. Remove/change the credentials from SMTP test server to ensure a message is not received before authenticating.

Measured by collecting and processing the logs that indicate connection status.

2.4.5.2 Validate the DataMotion Sandbox SMTP endpoint can receive messages to be sent via Direct.

Using SMTP test server configured properly from the last step, a test message with a test document can be sent through DataMotion SMTP endpoint. Measured by manually downloading the message in DataMotion Sandbox portal and comparing to the document sent.

2.5 Care setting

DataMotion Direct is certified to the §170.315(h)(2) criterion that covers the edge protocol connectivity.

All organizations that use XDR edge protocol for connecting to DataMotion HISP are acute care hospitals that use acute care setting. This is the only care setting in which Real World Testing by DataMotion will be conducted.

While DataMotion Direct is marketed to the healthcare organizations that operate in a broad of other care settings, they do not use edge protocols (XDR or SMTP) for connecting to DataMotion HISP and therefore are out of scope of DataMotion certification.

2.6 Expected outcomes

Expected outcomes are covered in the sections above.

2.7 Schedule & key milestones

Milestone	Target delivery date
Select customer(s) and partner(s) for participation in the RWT	December 1, 2021
Finalize the RWT plan based on feedback from the ONC-ACB	December 15, 2021
Begin collection of information as laid out by the plan.	January 1, 2022
Review intermediate results with customers and partners to make sure RWT protocols are effective.	February 2022
Follow-up to understand any issues arising with the data collection.	Quarterly, 2022
Data collection and review.	Quarterly, 2022

End of Real World Testing period/final collection of all data for analysis.	January 2023
Analysis and report creation.	January 15, 2023
Submit Real World Testing report to ACB (per their instructions)	February 1, 2023

3 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.

Authorized Representative Name: Alex Mushkin, VP, Products and Services

Authorized Representative Email: alexm@datamotion.com

Authorized Representative Phone: 973-993-7364

Authorized Representative Signature: *Alex Mushkin*

Date: 11/15/2021