



Pathology Results Implementation Guide

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1. Introduction

1.1 Purpose of Data Exchange Solution

Allows healthcare providers and pathology laboratories to submit electronic lab results containing pathology reports through MiHIN.

Pathology results, also known as a pathology report, is a medical report that describes a patient's tissue, blood, or organ samples and provides a diagnosis. Typically, the information from the report/result is used to help determine a diagnosis and treatment plan for a health condition or disease.

1.2 Message Content

For the purposes of implementation, Message Content refers to HL7® 2.xx, ORU^R01. HL7 v2.5.1 or newer version of HL7 is preferred; however, v2.3.1 is allowable.

1.3 Data Flow

1.3.1 Functional Data Flow

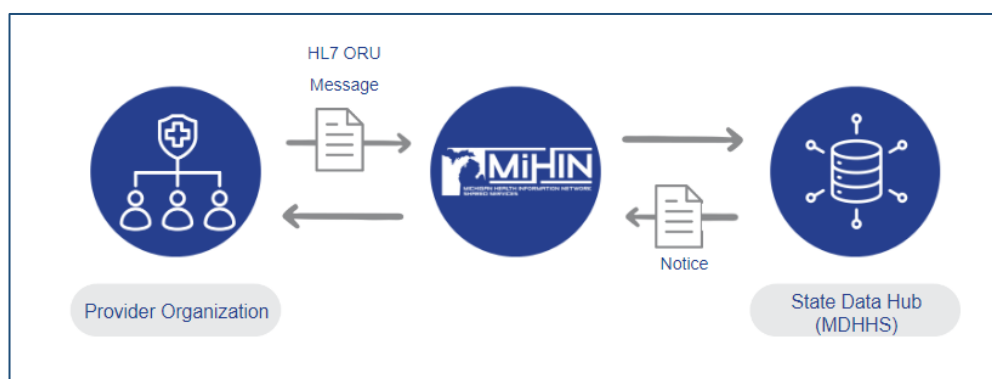


Figure 11. Data Flow for Pathology Results

1. The provider organization generates and sends reportable lab messages that contain pathology reports to MiHIN via an HL7 ORU message.
2. MiHIN receives the reportable lab message and routes it to the Michigan Department of Health and Human Services' (MDHHS) State Data Hub.

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3. Once the pathology report is received by the State Data Hub, it generates and sends a notice of receipt back to MiHIN.

For more information about all MiHIN data exchange solutions, please refer to the following link: [www. https://mihin.org/resourcehub/](https://mihin.org/resourcehub/).

1.3.2 Actors

- **Actor:** Provider Organization
 - *Role:* Generates and sends reportable lab messages containing pathology reports to MiHIN. Receives notices of receipt from MiHIN and ingests them into their Electronic Health Record (EHR).
- **Actor:** Health Information Network (MiHIN)
 - *Role:* Receives reportable lab messages from the participating provider organization and sends receipt notice back. Forwards reportable lab messages to the State Data Hub. Receives receipt notice from the State Data Hub.
- **Actor:** MDHHS Data Hub
 - *Role:* Receives reportable lab messages from MiHIN. Generates and sends a notice of receipt back to MiHIN.

You can contact MiHIN at [www.mihin.org/requesthelp](https://mihin.org/requesthelp) for more information.

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2. Onboarding

2.1 Prerequisites

Participating organizations should begin two parallel onboarding tracks simultaneously:

- Obtain, review, and execute legal agreements, and
- Establish technical transport and testing.

2.1.1 Universal Legal Prerequisites

The following legal documentation will need to be executed prior to any connectivity being established between MiHIN and participating organizations.

- Statement of Work (SOW), where applicable
- MiHIN's Exhibit A Agreement (Found on the MiHIN Legal Portal)
- Participant Agreement (Found on the MiHIN Legal Portal)
- Must select the appropriate data exchange solution (Pathology Results) on the MiHIN Legal Portal in addition to the above agreements.

To initiate the legal onboarding contact, email help@mihin.org.

2.1.2 Technical Requirements

The following data exchange solution implementations and technical requirements will need to be conducted for Pathology Results Data Exchange Solution to function.

2.1.2.1 Data Exchange Solution Requirements

There are no specific data exchange solution requirements for this data exchange solution.

2.1.2.2 Other Technical Requirements

- Ability to generate an HL7 ORU message containing pathology results.
- Ability to establish a VPN connection with MiHIN.
- Ability to receive the returned notice via established transport method and ingest it into the electronic health record (EHR) system.

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2.2 Pathology Results Onboarding Process

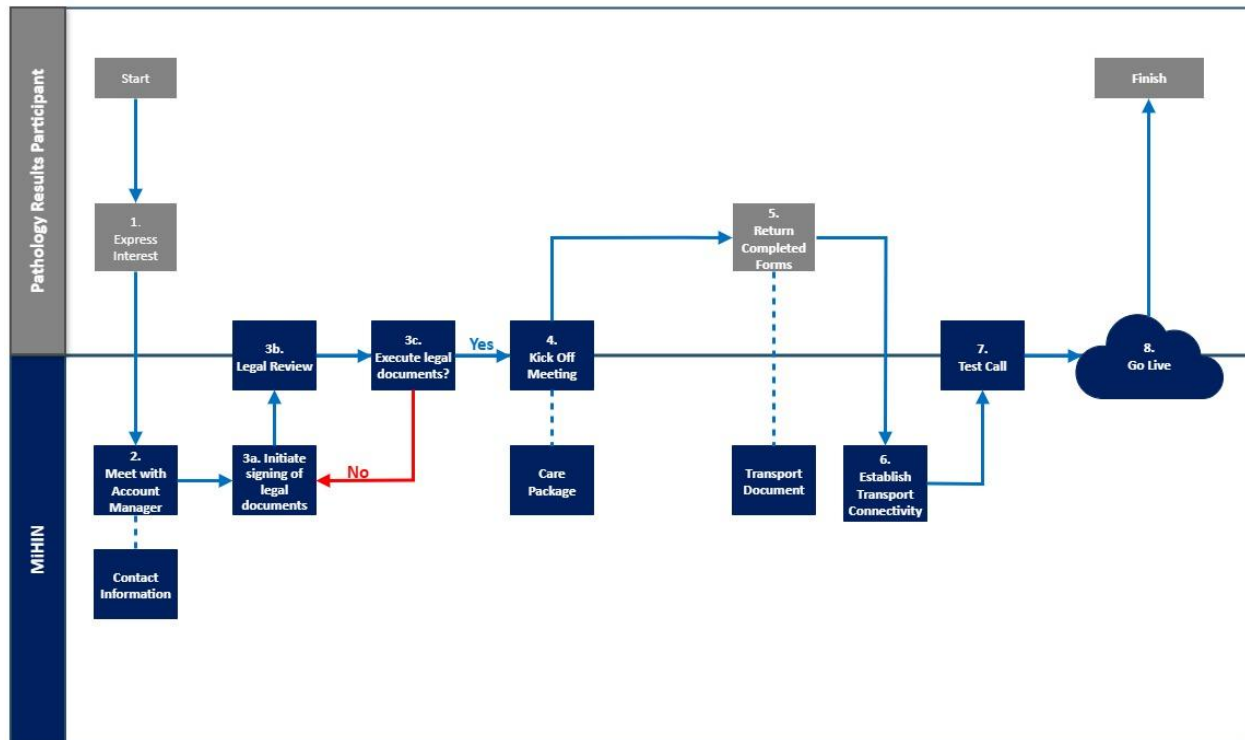


Figure 22. Pathology Results Onboarding Process Workflow

- Express interest in participating in the data exchange solution
- Execute legal documents
- Customer Success Team distributes Pathology Results care package
- Kick-off meeting with the Customer Success Team
- Exchange required documents
 - Transport Document
 - VPN Request Form
 - OID Request Form
 - Onboarding Contact Form
- Establish transport method/connectivity (VPN)
- Test Call
 - Test Reportable Lab Message
- Go Live

2.3 Technical Connectivity Process

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MiHIN considers itself “transport agnostic” and offers multiple options for organizations to establish technical connectivity to transport data to HIN. Organizations should select one or more connectivity methods for message transport based on their technical capabilities and should communicate the selection(s) to www.mihin.org/requesthelp early in the onboarding process. Currently the ONLY transport methods MiHIN accepts are:

- **LLP over IPsec VPN** – Lower-Layer Protocol over Internet Protocol Security Virtual Private Network

For VPN connectivity, two VPNs are required. A primary VPN will facilitate regular traffic. A secondary will be established for fail-over purposes.

The following steps describe the technical onboarding process. However, MiHIN typically conducts onboarding kick-off meetings with new organizations to go through each of these steps in detail and answer any questions.

1. The organization selects one or more supported transport methods and establishes connectivity with MiHIN. This step varies based on the method selected:
 - a. LLP over IPsec VPN – MiHIN’s site-to-site VPN request form must be completed, sent to, and approved by MiHIN. Send a request via www.mihin.org/requesthelp to obtain the VPN request form. A pre-shared key is then exchanged between the organization and MiHIN to initialize the connection. The LLP over IPsec VPN is the most efficient transport for very high volumes of messages.
2. Test messages are sent by the organization to MiHIN.
 - a. All test messages must have a “T” in the Message Header – field 11
 - b. Test traffic is routed via MiHIN to the appropriate destination. For Pathology Results, the destination is the MDHHS State Data Hub.
 - c. The end destination monitors for inbound test traffic and confirms receipt with MiHIN.
3. MDHHS declares the sending facility to be at production status after configurations are promoted from pre-production to production and a successful test transmission is completed in the production environment,

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during which the organization sends production messages and MiHIN confirms receipt.

- a. At this time, the sending facility may then send production messages through the participating organization to MiHIN. The sending facility now places a “P” (for production) value in the MSH-11 instead of the “T” used during testing.

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3 Specifications

3.1 Overview

3.1.1 Environments

- MiHIN Pre-Production
 - Public Rhapsody PROD IP: 52.204.207.180
- MiHIN Production
 - Private Rhapsody PROD IP: 172.16.5.125

3.2 General Message Requirements

3.2.1 Message Trigger Events

The HL7 message type for pathology results is an ORU and the trigger event is R01.

For general rules that apply to the entire message, refer to:

<https://www.naaccr.org/pathology-laboratory-electronic-reporting/>

3.3 Specific Segment and Field Definitions

3.3.1 Message Header

The definitions in the table below shall be conformed to by all HL7 messages communicating the message header segment.

Sequence	Length	DT	Usage	Cardinality	TBL#	Item #	Element Name	Comments
1	1	ST	R	1..1		00001	Field Separator	
2	4	ST	R	1..1		00002	Encoding Characters	
3	180	HD	R	1..1	0361	00003	Sending Application	
4	180	HD	R	1..1	0362	00004	Sending Facility	OID
5	180	HD	R	1..1	0361	00005	Receiving Application	MCSR
6	180	HD	R	1..1	0362	00006	Receiving Facility	MDHHS
7	26	TS	R	1..1		00007	Date/Time of Message	
8	40	ST	X	0..0		00008	Security	
9	7	CM	R	1..1	0076 0003	00009	Message Type	ORU^R01^ ORU_R01

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Sequence	Length	DT	Usage	Cardinality	TBL#	Item #	Element Name	Comments
10	20	ST	R	1..1		00010	Message Control ID	Should be repopulated (rather than pass-through) for outbound message header
11	3	PT	R	1..1		00011	Processing ID	P when in production, T for testing
12	60	VID	R	1..1	0104	00012	Version ID	
13	15	NM	X	0..0		00013	Sequence Number	
14	180	ST	X	0..0		00014	Continuation Pointer	
15	2	ID	X	0..0	0155	00015	Accept Acknowledgment Type	
16	2	ID	X	0..0	0155	00016	Application Acknowledgment Type	
17	2	ID	X	0..0		00017	Country Code	
18	16	ID	X	0..0		00692	Character Set	
19	60	CE	X	0..0			Principal Language of Message	
20	20	ID	X	0..0		00356	Alternate Character Set Handling Scheme	

3.3.2 All Remaining Segments

The message header is the only segment that MIHIN requires to be formatted in a certain way. As noted previously, please follow the registry specified standards for all remaining segment and field definitions: <https://www.naaccr.org/pathology-laboratory-electronic-reporting/>

3.3.3 Required Message Fields

- MSH-10: Message Control ID
- MSH-3.1: Sending Application Namespace ID

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- MSH-4.1: Sending Facility Namespace ID
- MSH-4.2: Sending Facility Universal ID
- MSH-9.2: Trigger Event
- PID-10: Race
- PID-11.1: Street Address
- PID-11.5: ZIP
- PID-2: Patient ID or PID-3: Patient Identifier List will be accepted
- PID-5.1: Patient Family Name
- PID-5.2: Patient Given Name
- PID-7: DOB
- PID-8: Sex
- PV1-2: Patient Class
- OBR-16: Ordering Provider
- OBX-11: Observation Results Status
- OBX-2: Value Type
- OBX-3: Observation Identifier
- OBX-5: Observation Value

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4. Production Support

	Severity Levels			
	1	2	3	4
Description	A critical production system is down or does not function at all, and there is no circumvention or workaround for the problem; a significant number of users are affected, and a production business system is inoperable.	More than 90% of messages received and delivered successfully, but some messages are not delivered/received with required accuracy. Service component severely restricted in one of the following ways: <ul style="list-style-type: none"> High impact risk or actual occurrence of patient care affected or operational impairment Business critical service has a partial failure for multiple TDSOs A critical service is online however, operating in a degraded state and having a significant impact on multiple TDSOs 	Service component restricted in one of the following ways: <ul style="list-style-type: none"> A component is not performing as documented or there are unexpected results Business critical service has failed two or more TDSOs Critical service is usable however, a workaround is available, or less significant features are unavailable 	No operational impact to MiHIN. A non-critical service component is malfunctioning, causing minimal impact, or a test system is down.
Initiation Method	<i>Call (844) 454-2443 and submit a ticket online at www.mihin.org/requesthelp</i>	<i>Call (844) 454-2443 and submit a ticket online at www.mihin.org/requesthelp</i>	Submit a ticket online at www.mihin.org/requesthelp	Submit a ticket online at www.mihin.org/requesthelp
Initial Response	Within 30 minutes	Within 30 minutes	Within 3 business hours	Within 6 business hours
Resolution Goal	<2 hours Restore Time from 7 am – 6 pm EST Monday-Friday and <4 hours nights, weekends and holidays	<4 hours Restore Time from 7 am- 6 pm EST Monday-Friday and <8 hours nights, weekends and holidays	<12 hours Restore Time from 7 am -6 pm EST Monday –Friday and <24 hours nights, weekends and holidays.	Within 5 business days

If you have questions, please contact the MiHIN Help Desk:

- www.mihin.org/requesthelp
- Phone: (844) 454-2443
- Monday – Friday 8:00 AM – 5:00 PM (Eastern)

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5. Legal Advisory Language

This reminder applies to all use cases covering the exchange of electronic health information:

The Data Sharing Agreement (DSA) establishes the legal framework under which participating organizations can exchange messages through the MiHIN Platform, and sets forth the following approved reasons for which messages may be exchanged:

- a. By health care providers for Treatment, Payment and/or Health Care Operations consistent with the requirements set forth in HIPAA
- b. Public health activities and reporting as permitted by HIPAA and other Applicable Laws and Standards
- c. To facilitate the implementation of “Meaningful Use” criteria as specified in the American Recovery and Reinvestment Act of 2009 and as permitted by HIPAA
- d. Uses and disclosures pursuant to an Authorization provided by the individual who is the subject of the Message or such individual’s personal representative in accordance with HIPAA
- e. By Data Sharing Organizations for any and all purposes, including but not limited to pilot programs and testing, provided that such purposes are consistent with Applicable Laws and Standards
- f. For any additional purposes as specified in any use case, provided that such purposes are consistent with Applicable Laws and Standards

Under the DSA, “**Applicable Laws and Standards**” means all applicable federal, state, and local laws, statutes, acts, ordinances, rules, codes, standards, regulations and judicial or administrative decisions promulgated by any governmental or self-regulatory agency, including the State of Michigan, the Michigan Health Information Technology Commission, or the Michigan Health and Hospital Association, as any of the foregoing may be amended, modified, codified, reenacted, promulgated or published, in whole or in part, and in effect from time to time. “Applicable Laws and Standards” includes but is not limited to HIPAA; the federal Confidentiality of Alcohol and Drug Abuse Patient Records statute, section 543 of the Public Health Service Act, 42 U.S.C. 290dd-2, and its implementing regulation, 42 CFR Part 2; the Michigan Mental Health Code, at MCLA §§ 333.1748 and 333.1748a; and the Michigan Public Health Code, at MCL § 333.5131, 5114a.

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It is each participating organization's obligation and responsibility to ensure that it is aware of Applicable Laws and Standards as they pertain to the content of each message sent, and that its delivery of each message complies with the Applicable Laws and Standards. This means, for example, that if a use case is directed to the exchange of physical health information that may be exchanged without patient authorization under HIPAA, the participating organization must not deliver any message containing health information for which an express patient authorization or consent is required (e.g., mental or behavioral health information).

Disclaimer: The information contained in this implementation guide was current as of the date of the latest revision in the Document History in this guide. However, Medicare and Medicaid policies are subject to change and do so frequently. HL7 versions and formatting are also subject to updates. Therefore, links to any source documents have been provided within this guide for reference. MiHIN applies its best efforts to keep all information in this guide up-to-date. It is ultimately the responsibility of the participating organization and sending facilities to be knowledgeable of changes outside of MiHIN's control.

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6. Appendices

6.1 Appendix A – Message Examples

6.1.1 Notice Message Example

MiHIN is content-agnostic and does not validate content for this data exchange solution beyond the message header. To enter fully into production, messages must conform to the registry's implementation guide as well: [North American Association of Central Cancer Registries Implementation Guide for Pathology Laboratory Electronic Reporting](#).

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7. Acronyms and Abbreviations Guide

ACK	HL7 Acknowledgment message
EHR	Electronic Health Record
HIN	Health Information Network
HL7®	Health Level Seven
MDHHS	Michigan Department of Health and Human Services
MiHIN	Michigan Health Information Network Shared Services
MSH	Message Header
NAACCR	North American Association of Central Cancer Registries
OID	Object Identifier
ORU	Observation Result
PO	Participating Organization
SOM	State of Michigan
TDSO	Trusted Data Sharing Organization
VPN	Virtual Private Network

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8. Definitions

Conforming Message. A message that is in a standard format that strictly adheres to the implementation guide for its Data Exchange Solution.

Data Exchange Solution Implementation Guide (DESIG). The document providing technical specifications related to message content and transport of message content between participating organization, MiHIN, and other TDSOs. use case implementation guides are made available via URLs in exhibits.

Data Exchange Solution Summary (DESS). The document providing the executive summary, business justification and value proposition of a use case. Use case summaries are provided by MiHIN upon request and via the MiHIN website at www.mihin.org.

Data Quality Assurance (DQA). The systematic process of ensuring data is accurate, complete, consistent, and reliable to support informed decision-making and reliable business operations.

Data Sharing Agreement. Any data sharing organization agreement signed by both MiHIN and a participating organization. Data sharing organization agreements include but are not limited to: Qualified Data Sharing Organization Agreement, Virtual Qualified Data Sharing Organization Agreement, Consumer Qualified Data Sharing Agreement, Sponsored Shared Organization Agreement, State Sponsored Sharing Organization Agreement, Direct Data Sharing Organization Agreement, Simple Data Sharing Organization Agreement, or other data sharing organization agreements developed by MiHIN.

Electronic Medical Record or Electronic Health Record (EMR/EHR). A digital version of a patient's paper medical chart.

Electronic Service Information (ESI). All information reasonably necessary to define an electronic destination's ability to receive and use a specific type of information (e.g., discharge summary, patient summary, laboratory report, query for patient/provider/healthcare data). ESI may include the type of information (e.g. patient summary or query), the destination's electronic address, the messaging framework supported (e.g., SMTP, HTTP/SOAP, XDR, REST, FHIR), security information supported or required (e.g., digital certificate) and specific payload definitions (e.g., CCD C32 V2.5). In addition, ESI may include labels that help identify the type of recipient (e.g., medical records department).

Health Directory. The statewide shared service established by MiHIN contains contact information on health providers, electronic addresses, end points, and ESI, as a resource for authorized users to obtain contact information and to securely exchange health information.

Health Information Network (HIN). An organization or group of organizations responsible for coordinating the exchange of protected health information (PHI) in a region, state, or nationally.

Health Information. Any information, including genetic information, whether oral or recorded in any form or medium, that (a) is created or received by a health provider, public health authority, employer, life insurer, school or university, or healthcare clearinghouse; and (b) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

Health Level 7 (HL7®). An interface standard and specifications for clinical and administrative healthcare data developed by the Health Level Seven organization and approved by the American National Standards Institute (ANSI). HL7 provides a method for disparate systems to communicate clinical and administrative information in a normalized format with acknowledgement of receipt

Health Provider means facilities/hospitals, health professionals, health plans, caregivers, pharmacists/other qualified professionals, or any other person or organization involved in providing healthcare.

Message Content. Information, as further defined in an Exhibit, which is sent, received, found, or used by a participating organization to or from MiHIN services. Message content includes the message content header.

Message Header (“MSH”) or Message Content Header. The MSH segment present in every HL7 message type that defines the message’s source, purpose, destination, and certain syntax specifics such as delimiters (separator characters) and character sets. It is always the first segment in the HL7 message, with the only exception being HL7 batch messages.

Message. A mechanism for exchanging message content between the participating organization to MiHIN services, including query and retrieve.

Michigan Department of Human Services (MDHHS). The state agency that oversees public health, Medicaid, and social services in Michigan, working to improve health and well-being across the state.

Michigan Health Information Network Shared Services. Michigan's state-designated, statewide Health Information Exchange.

MiHIN Infrastructure Service. Certain services that are shared by numerous use cases. MiHIN infrastructure services include, but are not limited to, Active Care Relationship Service (ACRS), Health Directory, (SCD), and MIGateway®.

MiHIN Services. The MiHIN infrastructure services and additional services and functionality provided by MiHIN allowing the participating organizations to send, receive, find, or use information to or from MiHIN as further set forth in an exhibit.

Negative Acknowledgment (NAK or NACK). "Not acknowledged" and is used to negatively acknowledge or to reject previously received message content or to indicate an error.

North American Association of Central Cancer Registries (NAACCR).

Notice. A message transmission that is not message content and which may include an acknowledgement of receipt or error response, such as an ACK or NACK.

Object Identifier (OID). Globally unique, structured numeric identifiers used to name and reference objects in a standardized way across systems.

Observation Result (ORU). The discreet value or set of values produced from clinical observation, measurement, or assessment, represented in accordance with HL7/FHIR.

Participating Organization. Any entity, institution, or group that formally agrees to take part in a program, project, or initiative.

Patient Data. Any data about a patient or a consumer that is electronically filed in a participating organization or participating organization participant's systems or repositories. The data may contain protected health information (PHI), personal credit information (PCI), and/or personal identifiable information (PII).

Provider Community. A healthcare provider with an active care relationship with the applicable patient.

Send / Receive / Find / Use (SRFU). It means sending, receiving, finding, or using message content. Sending involves the transport of message content. Receiving

involves accepting and possibly consuming or storing message content. Finding means querying to locate message content. Using means any use of the message content other than sending, receiving and finding. Examples of use include consuming into workflow, reporting, storing, or analysis.

Send/Receive/Find/Use (SRFU) activities must comply with Applicable Laws & Standards or State Administrative Code as that term is defined in this agreement and the data sharing agreement.

Trusted Data Sharing Organization (TDSO). An organization that has signed any form of agreement with MiHIN for data sharing.

Virtual Private Network. A secure connection technology that creates an encrypted tunnel between a user's device and a private network.