# TECHNICAL SPECIFICATION

ISO/TS 22691

First edition 2021-05

# **Health informatics — Token-based health information sharing**

# iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO/TS 22691:2021 https://standards.iteh.ai/catalog/standards/sist/e6016d38-c4ab-47a3-b386-fc5aca642f03/iso-ts-22691-2021



# iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO/TS 22691:2021 https://standards.iteh.ai/catalog/standards/sist/e6016d38-c4ab-47a3-b386-fc5aca642f03/iso-ts-22691-2021



# **COPYRIGHT PROTECTED DOCUMENT**

© ISO 2021

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office CP 401 • Ch. de Blandonnet 8 CH-1214 Vernier, Geneva Phone: +41 22 749 01 11 Email: copyright@iso.org Website: www.iso.org

Published in Switzerland

Co	<b>Contents</b> Pa					
For	eword	V   V   V   V   V   V   V   V   V   V				
Intr	roduction	<b>v</b>				
1	Scope	1				
2	•					
3						
4	Data items in HI-TOKEN  4.1 Overview  4.2 Item definitions	3				
5	Data types and value representations in HI-TOKEN  5.1 Overview  5.2 Data types and value representations	4				
6	Exchange format of HI-TOKEN  6.1 Overview  6.2 Electronic representation  6.3 Machine-readable optical representation  6.4 Printed text representation	5 5 6				
7	7.1.4 Data transfer 7.1.5 Encryption <u>ISO/TS 22691:2021</u> 7.1.6 https://dithentication.and/authorization <sup>016d38-c4</sup> ab-47a3-b386-					
8 Ann	Guidance for establishing a HI-community token sharing policy  nex A (informative) Comparison of IHE XDS/XDR and token-based health information sharing use cases.					
Ann	nex B (informative) Data flow of token-based health information sharing					
	lingraphy	22				

# **Foreword**

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see <a href="www.iso.org/directives">www.iso.org/directives</a>).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see <a href="https://www.iso.org/patents">www.iso.org/patents</a>).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see <a href="https://www.iso.org/iso/foreword.html">www.iso.org/iso/foreword.html</a>. (standards.iteh.ai)

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.socorg/members.html.

# Introduction

The interexchange of patient health information between healthcare facilities is important for both patients and the facilities to ensure the continuity and safety of healthcare and to reduce unnecessary examinations. Exchange of health information using IHE XDS is known as an effective solution for accessing patient health information in real-time when needed to provide care.

NOTE 1 Integrating the Healthcare Enterprise (IHE) Cross-enterprise Document Sharing (XDS) architecture and specifications. See <u>Annex A</u> for more information.

However, the ability to share information using IHE XDS technologies tends to require high cost to build and maintain the necessary infrastructure, and it is sometimes difficult for each healthcare facility to create the operational policy for the interoperable exchange of patient health information using that infrastructure. Therefore, media such as CD / DVD continues to be used for exchanging images and other health information (e.g. examination report, lab results, prescriptions, etc.).

In token-based health information sharing, each HI-TOKEN (health information token) contains metadata of a health information document stored in a repository. The HI-TOKEN includes the document ID, which identifies the specific document to be shared. Therefore, there is no need to search for the document using, for example, patient identifying information as search keys. This saves time for the recipient to locate and retrieve the shared document.

A HI-TOKEN can be provided to the patient, who can provide it to the referred healthcare facility at his / her discretion. The referred healthcare facility can then use the HI-TOKEN to retrieve the shared document. This process has the additional advantage that it allows the patient to provide implicit consent for the information exchange in that they are in full control of providing the HI-TOKEN to the receiving care service provider. (standards.iteh.ai)

Standardization of HI-TOKEN metadata and exchange formats minimizes the potential differences in interpretation between vendors implementing the corresponding systems, thereby contributing to the overall improvement of interoperability log/standards/sist/e6016d38-c4ab-47a3-b386-fc5aca642f03/iso-ts-22691-2021

NOTE 2 Annex B provides an example implementation and data flow for a health information sharing system using HI-TOKEN based exchange, including data content and token format examples.

# iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO/TS 22691:2021

https://standards.iteh.ai/catalog/standards/sist/e6016d38-c4ab-47a3-b386-fc5aca642f03/iso-ts-22691-2021

# **Health informatics — Token-based health information sharing**

# 1 Scope

This document specifies the data element content and exchange format for tokens used in token-based health information sharing. It includes

- a) the data items that may be contained in a health information token (HI-TOKEN),
- b) the value representation for each data item,
- c) the exchange formats allowed for HI-TOKEN sharing (electronic, machine-readable symbol, print), and
- d) considerations when establishing governance policies specifying how HI-TOKENs can be used within a specific group of healthcare organizations.

Provision is made for both physical media and electronic exchange media.

This document addresses the overall conceptual architecture and process for token-based health information sharing, as well as the role of patients, referring healthcare facilities, referred healthcare service providers, and health research institutions. Provision is made for pseudonymization of patient data.

This document only defines the specification of the HI-TOKEN used in token-based health information sharing. Data exchange / transport architectures, encryption methods, and specific governance policy requirements are outside the scope of this document 691-2021

# 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3166-1, Codes for the representation of names of countries and their subdivisions — Part 1: Country code

# 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <a href="https://www.iso.org/obp">https://www.iso.org/obp</a>
- IEC Electropedia: available at <a href="http://www.electropedia.org/">http://www.electropedia.org/</a>

# 3.1

#### metadata

attributes and related information about a set of data

### 3.2

# object identifier

globally unique identifier for an information object

Note 1 to entry: Object identifiers are standardized by standard developing organizations such as the International Telecommunications Union (ITU), ISO or IEC.

#### 3.3

# quick response code

# QR code

two-dimensional machine-readable optical symbol

Note 1 to entry: QR code formats are specified in ISO/IEC 18004:2015.

#### 3.4

# transport layer security

#### TLS

mechanism that enables use of a secure channel (communication path) for communication between various servers and clients using TCP/IP

Note 1 to entry: TLS is a suite of protocols managed by the Internet Engineering Task Force (IETF), with the foundational definition in RFC 1122.

#### 3.5

# health information token

# **HI-TOKEN**

metadata that enables secure exchange in token-based health information sharing

Note 1 to entry: HI-TOKENs can be exchanged in electronic representation, machine-readable optical representation, or paper.

Note 2 to entry: This is a specialized use of the general term "token" in that it refers to the data items and exchange formats specified for use in token-based health information sharing applications.

### 3.6

### universal serial bus

#### **USB**

digital interface for connecting up to 127 devices in a tiered-star topology

Note 1 to entry: The specification can be downloaded at www.usb.org.

### 3.7

# health information sharing community

#### health information community

# **HI-community**

group of facilities/enterprises that have agreed to work together using a common set of policies for the purpose of sharing health information using HI-TOKENs

Note 1 to entry: Membership of a facility/enterprise in one community does not prevent it from being a member of another community.

### 3.8

### demilitarized zone

#### DM7

logical and physical network space between the perimeter router and the exterior firewall

Note 1 to entry: The DMZ can be between networks and can be under close observation but it does not have to be so

Note 2 to entry: They are generally unsecured areas containing bastion hosts that provide public services.

# 4 Data items in HI-TOKEN

#### 4.1 Overview

<u>Clause 4</u> defines the data items in a HI-TOKEN. Each HI-community shall determine which data items are mandatory, optional or extended. Extended data items allow for the addition of content that can be necessary for real-world system implementations but is beyond the scope of this HI-TOKEN document.

#### 4.2 Item definitions

<u>Table 1</u> shows HI-TOKEN data item definitions. In addition to data Group and Item Names, <u>Table 1</u> specifies:

**Short form** Short form of an item name that may be used when long overall length of the HI-TOKEN

representation is not desirable (QR code for example).

**Optionality** Two types are identified: "R: Required" and "O: Optional". Items designated as "R" shall

always be included in the HI-TOKEN. Items designated as "O" are optional items that

may be included if available and appropriate.

**Type** Identifies the data type for value representation. For details of representation, see

Clause 5.

Description Specifies the detailed meaning for each data item.

ITEM STANDARD PREVIEV

 ${\bf Table 1-HI\text{-}TOKEN\ data\ item\ definitions}$ 

Group	Item	Short form	Optionality	Туре	Description
community	identifier	CMID		61d 66016d38-c4	The identifier assigned to the HI-community. The identifier shall be specified as an ISO OID (object identifier).
Community	name	directi do il directi det	1642f03/iso-ts-226	00010000 0 11	May contain the human-readable display name of the HI-community.
	identifier	SDID	0	id	May contain the identifier assigned to the sender organization by the HI-community or recognized in the community.
sender	name	SDNM	0	string	May contain the human-readable display name of the sender organization.
	contact	SDCT	0	string	May contain the contact (telephone, email etc.) of the sender organization
recipient <sup>a</sup>	identifier	RCID	0	id	May contain the identifier assigned to the recipient organization by the HI-community or recognized in the community.
	name	RCNM	0	string	May contain the human-readable display name of the recipient organization.
creation	timeStamp	CRTS	0	dateTime	May contain date and time the HI-TOKEN was created.
	identifier	PTID	0	id	May contain the patient ID assigned by the sender organization.
	anonymized	PTAN	0	boolean	May contain "true" or "false". "true" indicates that the information described in the patient has been anonymized while "false" indicates it has not been anonymized. If this data item is not present, or a null value is sent, the interpretation is "false" – that the patient information is not anonymized.
patient <sup>b</sup>	name	PTNM	0	string or hn	May contain the patient's full name. This data item may have a substructure defined to represent the details of a patient's name. See chapter 5 Data types and value representations in HI-TOKEN for the format definition of the hn data type.

<sup>&</sup>lt;sup>a</sup> "recipient" group may be repeated if the sender intends to send the document to multiple recipients. In some data formats such as JSON, it can be represented as an array.

b "patient" group may be repeated if the document includes information of multiple patients. In some data formats such as JSON, it can be represented as an array

Table 1 (continued)

	gender	PTGD	0	code	May contain a code to represent the administrative gender of patient.
					The following code is generally used:
					female
					male
					other
					unknown
					This specification does not prevent the use of other gender codes. A HI-community may define and use other gender codes.
	birthDate	PTBD	0	date	May contain the patient's date of birth.
	nationality	PTNT	0	code	May contain the code of country for patient nationality. Shall be used specified codes in ISO 3166-1 numeric.
	identifier	DMID	R	oid	Shall contain the identifier assigned to the document to be shared. The identifier shall be specified as an ISO OID (object identifier).
	description	DMDS	0	string	May contain the description of the document.
document	numberOfPatients DM	DMNP	0	integer	May contain the number of patients whose information is included in the document. For example, a document for a clinical study related to multiple individuals.
					O means the document is not related to individual patients. If this data item is not sent, or a null value is sent, the interpretation is that the document is associated with ONE patient.
decryption	password	iTeh S	STANDA (standar		May contain the password that will be used to decrypt the patient health information document. The algorithm to be used for encryption is not defined by this specification but should be decided according to the information sharing policy established between the sender and the recipient to ensure interoperability, both
			ISO/TS	22691:2021	within a single HI-community and cross communities.
other		https://standards.	teh.ai/catalog/stand fc5aca642f03/i	dards/sist/e601 so-ts-22691-2	This group may contain additional "extended" data items. These items should be included only after consultation between the sender and the recipient to ensure interoperability.

<sup>&</sup>lt;sup>a</sup> "recipient" group may be repeated if the sender intends to send the document to multiple recipients. In some data formats such as JSON, it can be represented as an array.

# 5 Data types and value representations in HI-TOKEN

# 5.1 Overview

<u>Clause 5</u> defines data types and value representations for data items contained in a HI-TOKEN. A HI-community may define and use extended data types.

# 5.2 Data types and value representations

Table 2 provides data type definitions used for a HI-TOKEN. It speficies:

**Data type** The name of the kind of value being represented.

**Length** The maximum available data length.

**Description** Detailed description of data type content.

<sup>&</sup>quot;patient" group may be repeated if the document includes information of multiple patients. In some data formats such as JSON, it can be represented as an array

Table 2 — Data type definitions

Data type	Length	Description
string	10240	Value representation by string. The number of characters is limited to a maximum of 10240 characters.
oid	64	An object identifier in ISO OID format <sup>a</sup> . The number of characters is limited to a maximum of 64 characters.
dateTime	25	Date and time representation with the form "YYYY-MM-DD" or "YYYY-MM-DDThh:mm:ss+zz:zz". The number of characters is limited to a maximum of 25 characters.
date	10	Date with a representation form "YYYY-MM-DD".
		A person or "human" name.
		Element <text> may contain a text representation of the full name.</text>
hn	- (No limit)	Element <family> may contain family name. In element <given>, first name, middle name, etc. may also be represented. If need to contain middle name(s), use multiple elements <given>, consider the last <given> as the first name, and the other <given> as the middle name(s).</given></given></given></given></family>
		Other elements may be defined and used.
id	64	Identifier using a combination of upper- or lower-case ASCII letters, numerals ('0''9'), '-' and '.'. The number of characters is limited to a maximum of 64 characters.
integer	11	A signed integer in the range -21474836482147483647 (32-bit).
boolean	5 iTeh S	"true" or "false" that represents truth value.
code	64	A string that has at least one character and no leading or trailing whitespace. The value is taken from a set of predefined strings (see Descriptions in Table 1). The number of characters is limited to a maximum of 64 characters.
<sup>a</sup> See oid-info.	com for information on	ISO/IEC/ITU object identifier formatting and registration.

fc5aca642f03/iso-ts-22691-2021

# 6 Exchange format of HI-TOKEN

# 6.1 Overview

There are three methods to represent a HI-TOKEN: electronic representation, machine-readable optical symbol, and text printed on paper. Implementations of HI-TOKEN document sharing within a HI-community may support one or more of these methods. Each method is described below.

# 6.2 Electronic representation

This document does not define the format of an electronic representation of a HI-TOKEN. Generally, a HI-TOKEN can be represented in XML, JSON, or Plain-Text. In real-world system implementations, the format should be agreed on by the sender and the recipient (see <u>Clause 8</u> for additional guidance).

Figure 1 displays an example of how a HI-TOKEN can be expressed in electronic representation using JSON.

```
{
           "community": {
              "identifier": "2.9999.1.9999",
              "name": "ISO Example DataExchangeService"
           "sender": {
              "identifier": "9999000001",
              "name": "HI-TOKEN Hospital"
           "creation": {
              "timeStamp": "2020-02-16"
           "patient": [
              {
                 "identifier": "1234567890",
                 "name": {
                    "family": "ISO",
                    "given": [
                      "iso",
                       "Iso"
          "gender": "N",
          "birthDate": "2017-09-29"
   "document": {
  "password": "13E9M5GH5M5SSWK808GC40WSG"
}
                          ISO/TS 22691:2021
```

Figure 1 = Example of jsoN encoded Hi-TokeN<sup>3-b386</sup>

# 6.3 Machine-readable optical representation

A HI-TOKEN can also be represented as a machine-readable optical symbol. Although this document does not define the type or format of a machine-readable optical symbol representing a HI-TOKEN, QR codes are widely used internationally and across industries. In order to minimize the required HI-TOKEN size in a QR code, data item "Short form" in Table 1 can be used.

The following is an example of QR code where the colon, i.e. ":", is used as a separator between item names in short form and the corresponding values while the forward slash, i.e. "/", is used as an item delimiter.

 $\underline{\text{Figure 2}}$  shows an example of how a HI-TOKEN can be expressed in machine-readable optical representation.