UMIN INDICE Lower level data communication protocol for CDISC ODM Specification

API Ver2.7

Specification for electronically sending clinical research data in CDISC ODM format to the UMIN INDICE

UMIN Center

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1 Overview

These documents explain lower level data communication specifications used to send clinical and epidemiological research data in Clinical Data Interchange Standards Consortium (CDISC) Operational Data Model (ODM) format to the Internet Data and Information Center for Medical Research (INDICE) system at the University Hospital Medical Information Network (UMIN) Center.

1.1 UMIN Center

The UMIN Center serves as an information network for the 42 national university hospitals in Japan. The Center is located at The University of Tokyo Hospital and provides services throughout Japan.

The UMIN Center began providing services via the Internet in 1993. All health care workers and researchers were able to use the services, regardless of their affiliation with national university hospitals. The UMIN is now a network infrastructure for research and education for all health care professionals and researchers.

1.2 INDICE

INDICE is a case registration (randomization) and data collection service for academic research.

As of May 2013, the number of registered cases exceeded 2,380,000, excluding the cases registered in the National Clinical Database (NCD), which is also supported by the UMIN Center.

When the INDICE system was first introduced, data for each case was entered online via a web browser. However, it is currently possible to enter case data in the CDISC ODM format.

1.3 CDISC

The CDISC is a nonprofit organization that works to standardize clinical data. The CDISC aims to establish an international standard for electronic acquisition, exchange, application, and archiving of clinical data and

metadata of medical and pharmaceutical products.

The CDISC Standards are a set of the standard specifications defined by the CDISC.

1.4 ODM

ODM is one of the standard groups defined by CDISC to exchange and save data. ODM is also used for data archiving. Data files are in the XML format.

1.5 Advantages of data registration in the ODM format

It used to be both time- and cost-intensive to modify the data specifications of electronic medical records or use the Electronic Data Capture (EDC) system to send data to the registration server. Now that the ODM format has been adopted as the international standard of data registration, the systems for sending electronic medical records as well as the EDC are able to accommodate multiple systems with one-time function implementation. The advantages of this are reductions in time and cost. This system is also expected to reduce the preparation period of each project before the start of the trial.

2 Preparation

The following procedures and preparations are necessary to send data in CDISC ODM format to the UMIN INDICE.

2.1 Signing up for INDICE

First, you need to sign up for INDICE to use the UMIN INDICE service. If you are working on a case collection project that has already started and you want to begin sending data in the CDISC ODM format, you do not need to sign up again. However, you should seek approval from the project office in advance.

2.2 Development tasks for UMIN

If you want to collect data in the CDISC ODM format for your clinical research project, more time than the standard development period of INDICE will be needed.

For projects that have already been started, separate development tasks for each project will be needed to collect clinical data in the CDISC ODM format.

2.3 Development tasks for data senders

Data senders such as hospitals should use functions to output case data in the CDISC ODM format and to transmit the output data. In general, you need a function to transmit the case data stored in the EHR or EDC systems via the internet to the UMIN INDICE in the CDISC ODM format.

Similarly, you will need eCRF, an entry form for case data, and an edit checking function.

2.4 Structure of UMIN INDICE

There are three types of systems in the UMIN INDICE: a production system, a test system, and a development system.

The development system is mainly used for developing systems inside the UMIN Center.

First, the system that will be used for your project is developed for the UMIN INDICE using the development system at the UMIN Center. The system is then migrated to the test system. During the time this takes, you need to develop a client program for data transmission to test the transmission program in the test system environment.

Once sufficient testing of the system is completed, the system is migrated to the production system to be used for clinical research trials in INDICE.

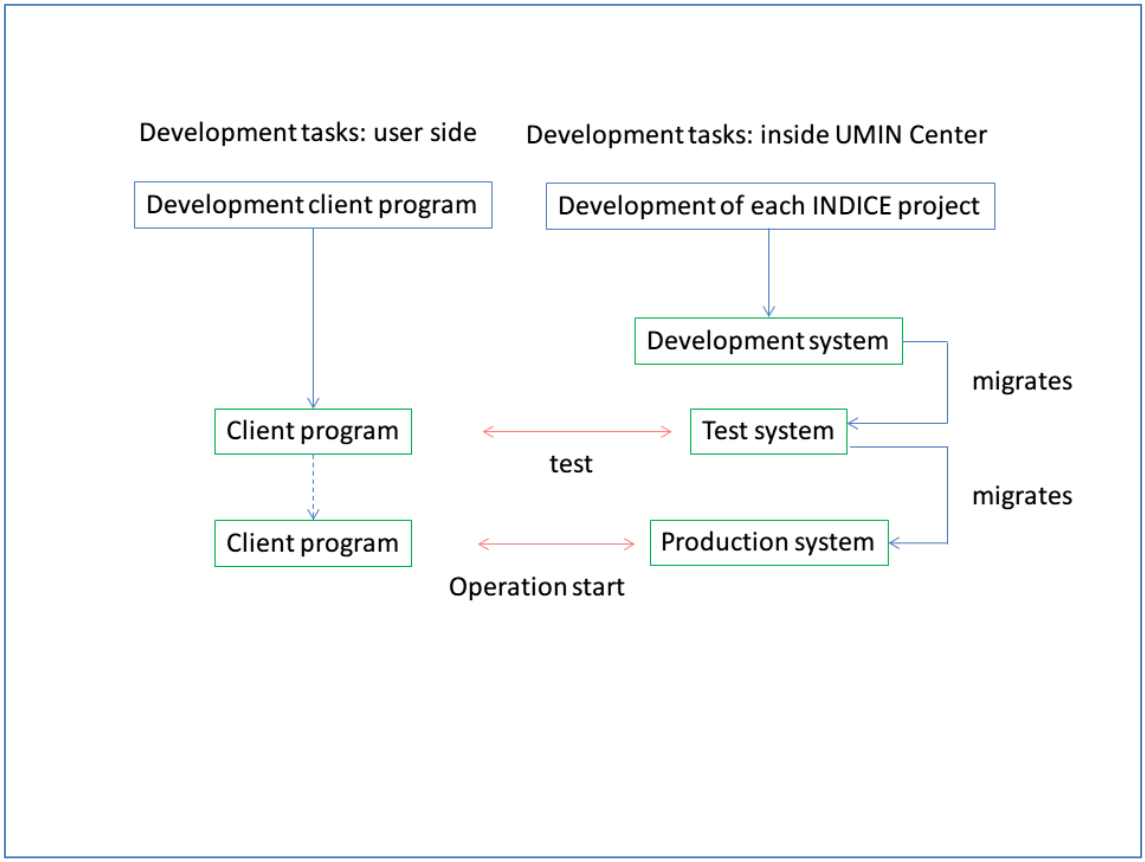

Figure 1. Development Flow

3 Specification

The following are the specifications for the lower level data communication protocol when sending case data in the CDISC ODM format to UMIN INDICE.

3.1 Specification for transmission

Table 1. Specification for transmission

Item	Content
Transmission method	SOAP
Encryption method	SSL
Authentication method	Basic Authentication
Character code	Shift-JIS
Line feed code	Only LF
Location of WSDL	https://c.umin.ac.jp/cdms/(Project_number)/Odm.wsdl

- Port number is 443 in the SSL and https
- Authentication is required by the INDICE system with a UMIN ID and password with basic authentication
- Line feed code is only LF, CR is not used
- "cdms_test" is used instead of "cdms" if the test system is in WSDL
- "cdisc_test" is used instead of "cdisc" if the test system is a SOAP object
- (Project_number) is the project number that is set in the UMIN INDICE. It generally will be a number such as "P0231"

3.2 SOAP method

The call method for a SOAP object in the UMIN INDICE server is as follows.

Table 2. Call method

Method name		sendODM2		
Processing		Program performs a series of storage processes to create a file of data in CDISC ODM format with the given filename in the server		
Argument/Return code		Meaning		Data type
Argument	Argument1	File name to upload		String
	Argument2	ODM data file		String
Return code		Success	(Registration number of INDICE)	String
		Failure	001:Failed sending data	
			002:Failed to save CDISC table	
			003:Failed to save INDICE	
			004:Internal server error	
			From 005 to 999 reserved	

- Although INDICE registration numbers differ for each project, they generally begin with “E”; for example, “E0235”.
- Processing has succeeded when the return code of the processed result from method is the same as the number of the INDICE registration number. The client system needs to associate this registration number with the sending data. This registration number is necessary to specify the case when confirming the registered case via the web in the UMIN INDICE.

4 Use of the registration number

When the case data are successfully registered in the UMIN INDICE, a registration number is returned from the UMIN INDICE server as the return code. Please keep this registration number to manage cases on the client side.

This number can be also used to identify the case data registered for the project in the UMIN INDICE system.

The Figure 2 shows an example of the screen you can use to check for saved data in INDICE with the registration number.

The registration number shows the example of “E0000003”.

Figure 2. Example of specifying the case via Web

5 Supplement for ID and password to access the INDICE

A UMIN ID is required to use the UMIN INDICE. The UMIN ID should be configured to permit access the INDICE system and to the research project to which you send clinical data.

If you do not have a UMIN ID, you first need to get one and then follow the required procedures to access the research project. You should meet the conditions for authentication, or you should access the INDICE system to perform a transmission test in the CDISC ODM format after developing a data transmission program.

There are two types of passwords for use of the services provided by the UMIN Center. This means that two different passwords could be issued for one UMIN ID. One is a general password to use the services other than INDICE, such as e-mail and the online training evaluation system (EPOC). The other is a password for using the INDICE.

- General password: To use e-mail and normal UMIN service
- INDICE password: To use INDICE only

Two passwords will be issued, even if you only use INDICE.

You can access the INDICE system if an INDICE password is issued

You can access a specific research project if your UMIN ID is set to be accessible by the UMIN Center.

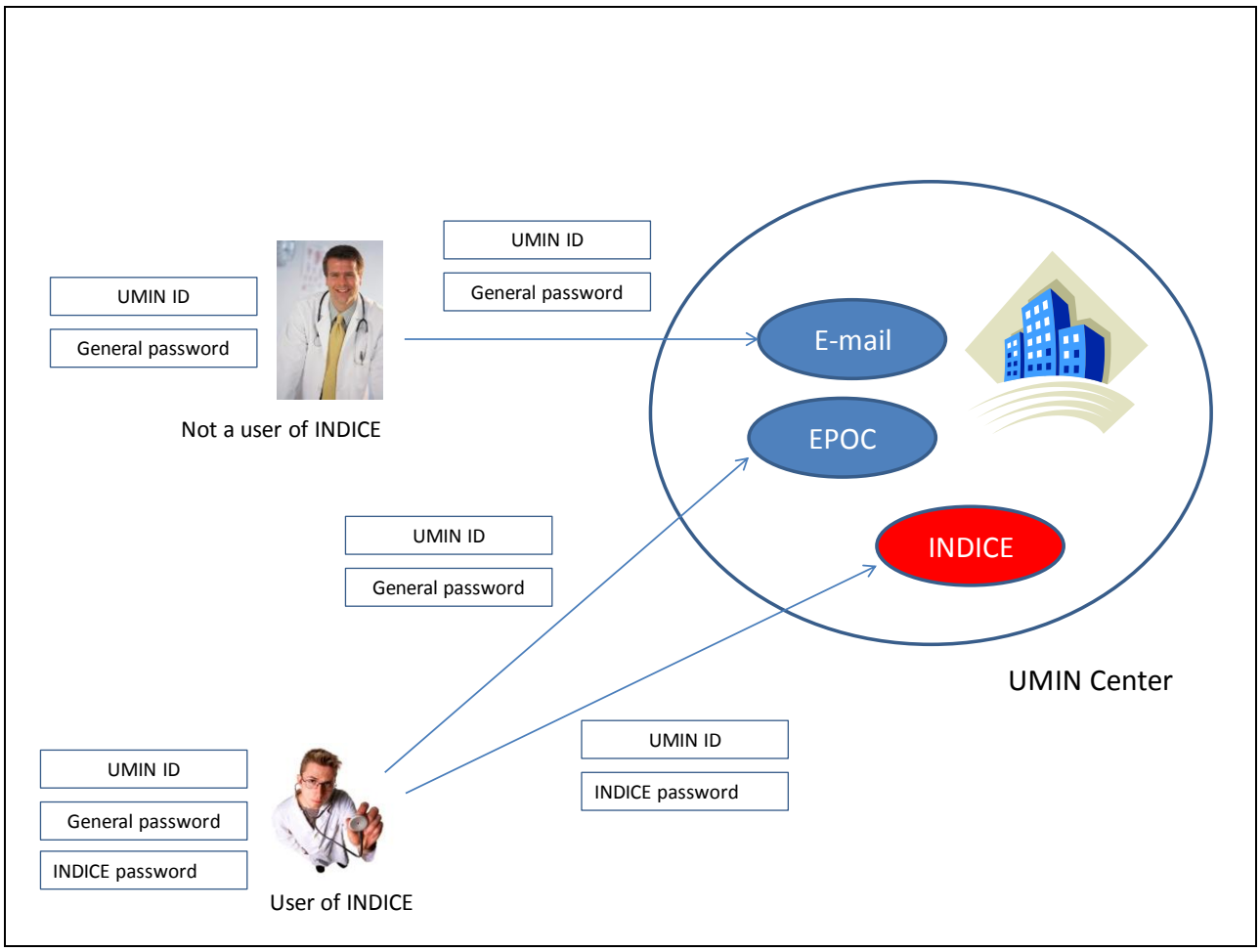

Figure 3. Service and Password of UMIN Center

6 Change log

Ver1.0	First version (for the Fukushima-Univ. Project)
Ver1.1	Improved data transfer (for EHR of Cardiology)
Ver1.2	Changed entryINDICE without arguments to strengthen security and improve independence of each study
Ver1.3	Changed the arguments of entryINDICE to UMIN ID and change the return code to the registration number
Ver2.0	Added WSDL support
Ver2.1	Created an independent three-methods version (for LMISC, J-RBR, e.g., kidney disease)
Ver2.2	Changed how to specify UMIN ID, a UMIN ID is described by the LoginName in the User Elements in the Administrative Elements in ODM
Ver2.3	Added the function to notify return code (001-003)
Ver2.4	Added SOAP method integration (entryINDICE integration)
Ver2.5	Added return code (004)
Ver2.6	Added a function to notify the INDICE registration number when the registration succeeds
Ver2.7	Modified document structure