



**UMIN INDICE Lower  
level data  
communication  
protocol for CDISC  
ODM Specification**

*API Ver2.7.1*

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

**UMIN Center**  
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## 1 Overview

These documents are the specifications for the lower level data communication protocol for CDISC ODM at the time of sending clinical and epidemiological research data in CDISC standards ODM format to INDICE system in UMIN Center.

### 1.1 UMIN Center

UMIN (University hospital Medical Information Network) Center is an organization which provides a network composed of the 42 national University Hospital of Japan. The Center is located in the University of Tokyo Hospital and provides services to the whole Japan.

UMIN Center began to provide services through the Internet in 1993, and medicine or medical personnel besides ones belonging to the national university Hospital became able to use the services. Now, the network UMIN provides becomes the study education infrastructure that all medicine or medical personnel can use.

### 1.2 INDICE

INDICE (Internet Data and Information Center for Medical Research) is the service to register and collect (randomized) cases of the clinical epidemiologic studies which researchers lead as scientific studies.

As of January 2013, the total number of cases registered by each project exceeds 2,220,000 except the enrollment in NCD (National Clinical Database), which UMIN Center supports in the same way.

INDICE has been the system to which case data is inputted only from the web browser, but now in addition to the input via the web browser, it is also available to register case data in the CDISC ODM format.

### 1.3 CDISC

CDISC (Clinical Data Interchange Standards Consortium) is a nonprofit clinical data standardization group. CDISC aims at the establishment of international industry-wide standard which helps to electronically acquire,

exchange, apply for, and archive the clinical data of pharmaceutical products and meta-data.

CDISC Standards is the set of the standard specifications that this CDISC prescribes.

## 1.4 ODM

ODM (Operational Data Model) is one of the standard groups which CDISC defines. This is a specification for the exchange and the preservation of data. This is also available for data archiving. The structure is a file in XML format.

## 1.5 Merit of registration data in ODM format

It was a big burden period cost typical work or enhancement modifications each time the system occurs to fit the data specifications of the registration destination server EDC system side and electronic medical records as a data sending side in the past. This time, will be available on more than one system in function implementation of once in the system in the data registration side, such as EDC and electronic medical records by corresponding to the data registration of ODM format, an international standard. There are benefits that can significantly reduce the burden these from this. I can be expected that the preparation period up to the start of the test of each project is also reduced.

## 2 Preparation

Some procedures and preparations are necessary to perform the data sending in the CDISC ODM format with UMIN INDICE.

### 2.1 Sign up for INDICE

INDICE application is necessary before you use UMIN INDICE. When you want add a function of the data sending in the CDISC ODM format to the case collection project that has been already started, you do not need to sign

up over again, but you must get approval of the project office in advance.

## 2.2 Preparing for UMIN

In UMIN INDICE if you want to collect data in the CDISC ODM format from the clinical research project, we take additional time to correspond to the CDISC ODM format in addition to the development period of standard INDICE.

If you want to add a function to collect clinical data in the CDISC ODM format to projects which are already running, it must take more time to accomplish it for each project.

## 2.3 Preparing for Data sender

It is necessary for a data sender as a hospital to implement functions to output case data in the CDISC ODM format and to transmit the output data. Generally, you need a function to transmit case data stored in EHR or EDC system via the internet to UMIN INDICE in the CDISC ODM format.

Similarly, you need eCRF or an entry forms for case data and the check function to edit.

## 2.4 Structure of UMIN INDICE

Three kinds of systems, a production system, a test system, and a development system, have been running in UMIN INDICE.

The development system is mainly used for development tasks inside UMIN Center.

When you begin to send the clinical data in the CDISC ODM format to UMIN INDICE, at first, in order for you to carry it out, we need to develop it on the development system inside UMIN Center. After our development finish, the system that we developed for you migrates from the development system to the test system. On the other hand, you also need to develop a client program for transmission in advance. It is necessary to test the transmission program in the test system environment.

After sufficient testing completes, the system migrates to the production

system. Finally, use of clinical research trials in INDICE practically starts from that point.

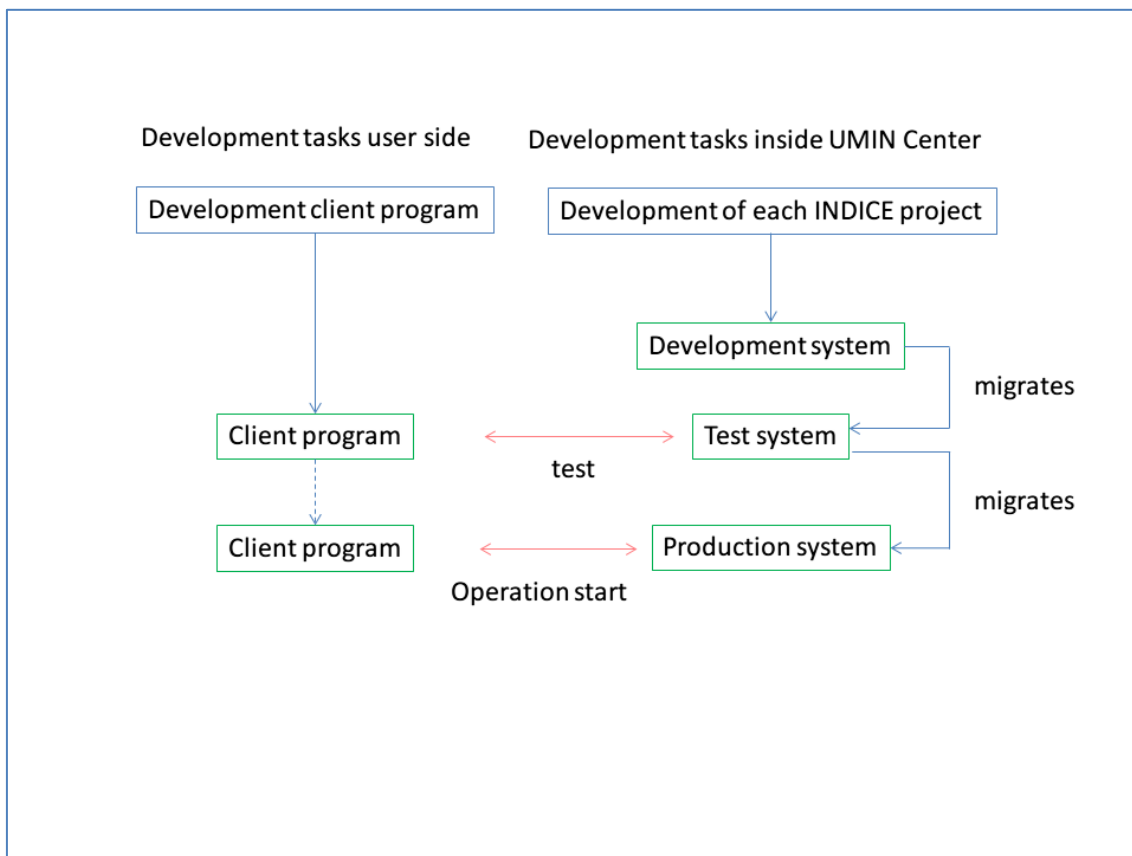


Figure 1 Development Flow

### 3 Specification

This is a specification for the lower level data communication protocol for CDISC ODM 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	<a href="https://c.umin.ac.jp/cdms/(Project_number)/Odm.wsdl">https://c.umin.ac.jp/cdms/(Project_number)/Odm.wsdl</a>

- Port number is 443 in the SSL and https
- Authentication is required by INDICE system with UMIN ID and password in basic authentication
- Line feed code is only LF, CR is not used
- Use “[cdms\\_test](#)” for “[cdms](#)” if the test system in WSDL
- Use “[cdisc\\_test](#)” for “[cdisc](#)” if the test system in SOAP Object
- ([Project\\_number](#)) is the project number that is set in UMIN INDICE. It will be a number such as “P0231”, generally

### 3.2 SOAP method

Call method for SOAP object in UMIN INDICE server is as follows.

**table 2 Call method**

Method name		sendODM2		
Processing		Program performs a series of store process 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	String	
Return code		Success	(Registration number of INDICE)	
		failure	001:Failed sending data	String
			002:Failed to save CDISC table	
			003:Failed to save INDICE	
			004:Internal server error	
From 005 to 999 reserved				

- Although INDICE registration number depends on the settings for each of projects in INDICE, it generally begins with “E”. For example, it is a number such as “E0235”.
- When the return code of the processed result from method is the same as the number of the INDICE registration number, it means that the processing succeeds. Client system side needs to associate this registration number with sending data and to keep it. This registration number is necessary to specify the case at the time of confirming the registered case via the web browser in UMIN INDICE.



#### 4 Use of registration number

When the case data is successfully registered in UMIN INDICE, registration number as the return code is returned from UMIN INDICE server. Please acquire this registration number on the client side and use for management of cases.

In addition, it can be also used to identify the case data which is registered in the project in UMIN INDICE system.

The following figure 2 is an example of the way you can see saved data in INDICE by using a registration number form the web browser.

The registration number shows the example of “E0000003”.

Registration number, click here



Figure 2 Example of specifying the case via Web

## 5 Supplement for ID and password to access the INDICE

UMIN ID is required to use UMIN INDICE. UMIN ID must be able to access to the system for INDICE, and also it must be permitted (registered) to access to the research project to which you want to send clinical data in the CDISC ODM format by UMIN Center.

If you do not have UMIN ID, you need to get UMIN ID at first and also need to follow the necessary procedures for access to the research project. In addition, you must meet these conditions for the authentication or for access to the system for INDICE when you need to perform a transmission test in the CDISC ODM format after developing a data transmission program.

UMIN ID to use services that UMIN Center provides has two kinds of passwords. According to services, two different passwords are issued to one UMIN ID. One is a general password for using services other than INDICE of UMIN Center, such as e-mail and 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 use only INDICE.**

The state in which it is accessible to INDICE is the state in which INDICE password is issued

The state in which it is accessible to the research project is the state in which UMIN ID is set to access to the research project by UMIN Center.

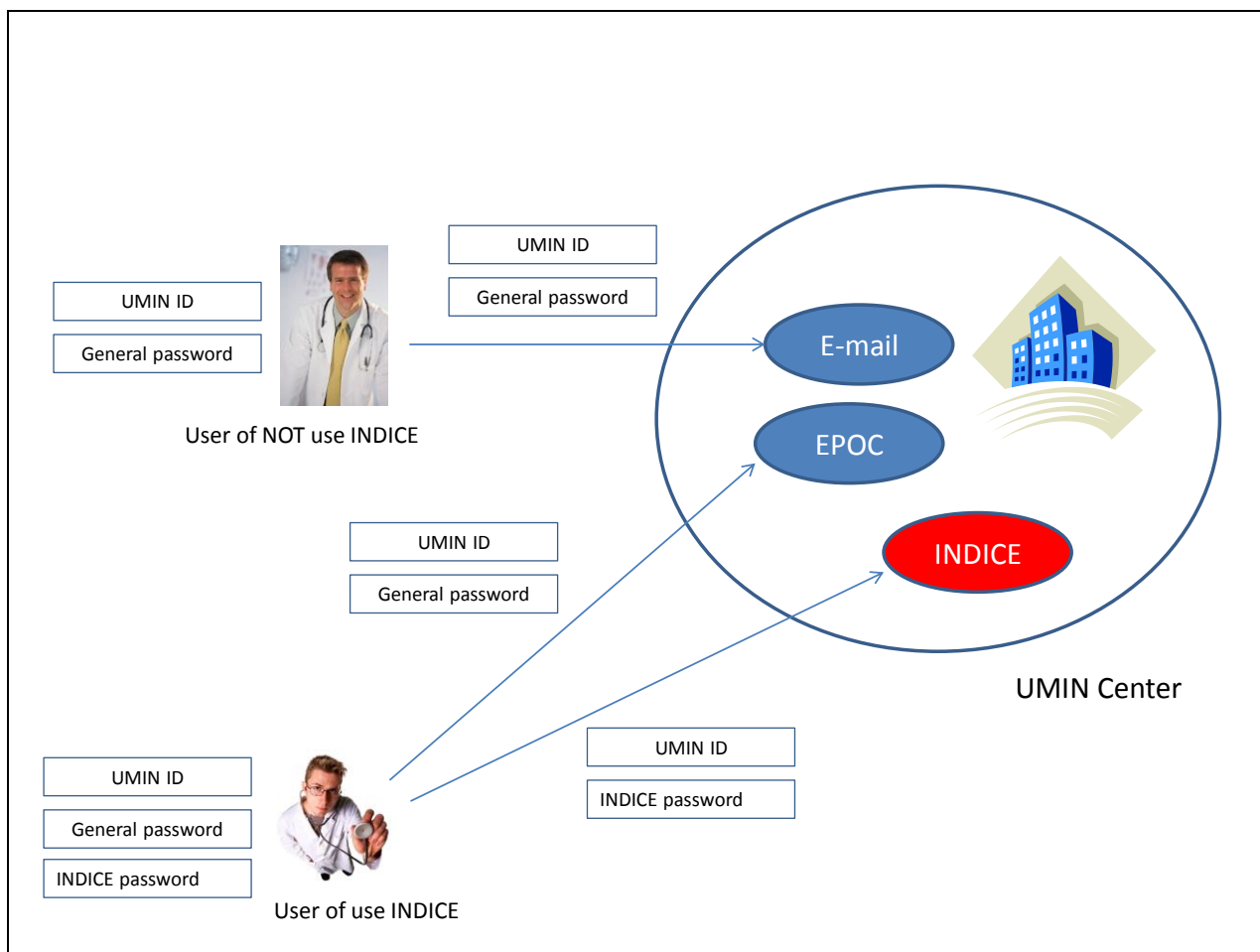


Figure 3 Service and Password of UMIN Center

## 6 Change log

Ver1.0	First version (For Fukushima-Univ. Project)
Ver1.1	Improved data transfer (For EHR of Cardiology)
Ver1.2	Change entryINDICE without arguments to strengthen security and improve independence of each study
Ver1.3	Change the arguments of entryINDICE to UMIN ID and change the return code to the registration number
Ver2.0	WSDL support
Ver2.1	Independent three methods version (For LMISC, J-RBR (kidney disease))
Ver2.2	Change how to specify UMIN ID, 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	SOAP method integration (entryINDICE integration)
Ver2.5	Added return code (004)
Ver2.6	Added the function to notify INDICE registration number when the registration succeeds
Ver2.7	Modify of document structure

Ver2.7.1

Errors corrected