

ODIN ver 0.8 Beta End User Documentation

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1 INTRODUCTION

1.1 Product Identification

This is the user documentation for the OpenClinica Data Importer web application (ODIN).

1.2 Purpose of the document

The purpose of this document is to provide the detailed user guide for the application.

1.3 Intended Audience

This guide is intended for OpenClinica users who would like to import data from a comma separated values (csv) file into OpenClinica.

2 GENERAL DESCRIPTION

2.1 Product Perspective

This application will make it possible to import subjects to OpenClinica from a (comma separated values) .csv file, schedule events for the subjects and import data from the .csv file. The application will transform the provided .csv data into a CDISC ODM XML structure.

2.2 Product Availability

This application is available from June 2015. ODIN source code with the user documentation can be downloaded from www.rdcit.org and also can be found on GitHub. Updates for ODIN will be published through the same channels.

2.3 General Constraints

The application requires PHP 5.3+ to be installed and PHP PDO support for PostgreSQL to be enabled on the web server.

CAUTION: This application introduces a complex procedure of importing legacy data in OpenClinica. Usage of this product requires expertise level knowledge of OpenClinica. Furthermore your OpenClinica username must be authorised to use the web services in order

to login to ODIN. Please make sure you read this document carefully before using the application.

2.4 License

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3 USER GUIDE

3.1 Installation

To install this application download the odinbeta.zip from www.rdcit.org, upload it to your webserver's document root directory and extract it. Edit the default settings file (odinbeta/settings/example.inc.php) and provide the required information. An OpenClinica instance name must be provided. This name will be displayed on the login screen. The \$ocUrl variable should contain your URL to that OpenClinica instance. Provide the proper credentials for your database and the URL to your OC web services. After finishing the changes save this file as "whatevernameyouwant.inc.php". If you want to connect multiple OpenClinica instances to ODIN you have to reopen example.inc.php and provide the required information and save as "somethingelse.inc.php". All .inc.php (except the example.inc.php) will be used when determining the connected OpenClinica instances on the login screen. Make sure your web server has the proper rights to read and write all files and directories in the application.

3.2 Logging in

To login to ODIN visit the following URL: <http://yourwebserver.com/odinbeta> where you should be able to see the ODIN login screen.

OpenClinica Data Importer web application

Please log in!

Login

OC Username:

OC Password:

OC Instance:

OC Anon

Login

ODIN Beta - ver 0.8 Developed by Csaba Halmagyi@RDCIT

To log in you have to choose an OpenClinica instance and enter your OpenClinica username and password. Your username should be authorised to use the web services.

3.3 ODIN Main menu

After a successful login the ODIN Main menu will be displayed.

OpenClinica Data Importer web application

Home Profile Templates Logged in as: **ch686** (Logout)

Select a study > Upload data file > Validate data file > Import subjects > Schedule events > Upload mapping file > Define CRF versions > Mapping > Create XML > Import

Select a study:

Default Study

Please choose a file:

Browse...

 No file selected.

Upload File

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You can always return to this screen by clicking the Home menu.

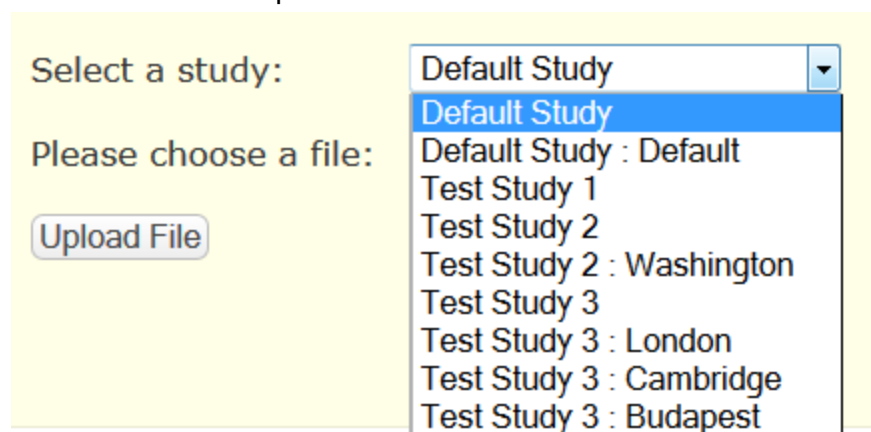
NOTE: Please don't use the web browsers back button to go back to the previous page as ODIN may lose some critical information. If a user has to restart the importing process the Home menu should be used.

3.4 Creating a CDISC ODM XML

In order to import data to OpenClinica you have to create a CDISC ODM XML file. Follow the steps below:

3.4.1 Select a study and upload a data file

Go to the Main menu. This screen will display all the active studies and sites assigned to the current user in a dropdown list.



The screenshot shows a web form with a yellow background. On the left, there is a label 'Select a study:' followed by the text 'Please choose a file:'. Below this text is a button labeled 'Upload File'. To the right of the text is a dropdown menu. The dropdown menu is open, showing a list of studies. The first item is 'Default Study', which is highlighted in blue. Below it are 'Test Study 1', 'Test Study 2', 'Test Study 2 : Washington', 'Test Study 3', 'Test Study 3 : London', 'Test Study 3 : Cambridge', and 'Test Study 3 : Budapest'.

In this example the user is assigned to four studies (Default, Test Study 1, 2, 3). Test Study 1 does not have any sites, while Study 2 has one site (Washington). Select a study or a site you would like to import against. Browse your computer to find your csv data file and click "Upload file".

3.4.1.1 The .CSV data file

In order to use ODIN users must create a data file to store the details about their subjects and their data.

The data file structure is the following:

	A	B	C	D	E	F	G	H	I
1	SubjectId	SecondaryId	EnrollmentDate	PersonId	Gender	DOB	GeneralHealth	GP visits	HaveAsthma
2	DV001		2015-04-01	pid01	M	1950-02-17	1	0	1
3	TT001		2015-04-01	pid02	M	1961-03-04	5	0	2
4	PLO001		2015-04-01	pid03	F	1963-08-11	4	1	2
5	HP001		2015-04-01	pid04	M	1985-11-01	4	2	2
6	GTW001		2015-04-01	pid05	M	1910-12-20	3	2	2
7	CJS001		2015-04-01	pid06	M	1958-04-23	5	2	2
8	IJ001		2015-04-01	pid07	M	1948-07-30	4	1	2
9									
10									
11									

The first six columns are mandatory and have to be in the same order as shown above. Users can download a template data file from ODIN's Templates menu. The first column stores the unique Study Subject ID which should never be empty. If the study was set up to use the Secondary Id and/or the Person ID, users should provide that information as well. Enrollment date can be entered or can be left blank. If it is blank ODIN will use the current date for the Enrollment date. If the study was set up to collect gender information, there should be an F or an M otherwise it can be blank. If the study was set up to collect the subject's date of birth the DOB column should contain a value for every subject. If the study was set up to collect year of birth only the column can contain either a full date of birth or the year of birth only.

NOTE: All date values in the data file should be in ISO 8601 format (YYYY-MM-DD). MS Excel may change the date format in your data file. We strongly suggest to use a CSV editor instead.

Apart from the mandatory columns the data file may contain one or more data columns. These columns will hold the data which will be mapped to the CRF items. The example file (see above) contains the six mandatory fields and three data fields (GeneralHealth, GP visits, HaveAsthma).

Users are not allowed to use double hashes (##) in their data files as values. Double hashes are used by ODIN to separate OIDs while converting the data.

3.4.1.2 Repeating item values in data file

Repeating item values should start with double colons (::) and be stored in the same cell. Excel shortcuts for editing cells can be found on our page. Please visit <http://rdcit.org/> for more help.

K	L
Incidents	ICD10 code
::Emotionally unstable personality disorder	::F60.3
::Fracture of nasal bones::Concussion	::S02.2::S06.0
::Fall from cliff::Hit by another person::Exposure to excessive natural cold	::W15::W50::X31
::Accident to watercraft causing other injury::Fall from cliff	::V91::W15
::Hit by another person	::W50

In this example we have two repeating items one of them is to store the disease/accident name and the other is to store the ICD10 code referring to that disease/accident. In our example the second subject had two incidents (Fracture of nasal bones, Concussion). Even if the subject only has one repeating item value (such as the first subject) the value should be preceded by double colons.

3.4.2 Validate your data file

ODIN has some basic validation scripts built in which run after a data file has been uploaded. If the user has any errors in their data file ODIN will notify them about these errors. It will also tell them about the first occurrence of the error. Any errors have to be fixed before continuing to the subject import. Please note that during this step only the first six columns will be validated by the application. After creating and uploading the CDISC ODM XML file to OpenClinica other errors (such as invalid data values, etc) can be shown.

3.4.3 Import subjects

ODIN will try to import all subjects in your csv data file and display the results for each subject. When you import a new subject to OpenClinica ODIN will create the subject and retrieve the OID.

```
createSubject:Success
Subject name in csv: IJ001
SOID = SS_IJ001 label = IJ001
```

Subjects import finished.

Subj OIDs retrieved: 7
New subjects: 7
Errors: 0

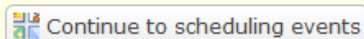
 Continue to scheduling events

If you try to import a subject which has already been enrolled in the study ODIN won't import the subject but will retrieve the OID:

```
createSubject:A subject with the Person ID: johnsmith is already enrolled in this study.  
Subject name in csv: IJ001  
SOID = SS_IJ001 label = IJ001
```

Subjects import finished.

Subj OIDs retrieved: 7
New subjects: 0
Errors: 0

 Continue to scheduling events

3.4.4 Schedule events

After importing the subjects into OpenClinica we need to schedule the events we want to import data against. ODIN will display all events in the current study with all the CRFs assigned to them. Any repeating events in the study will be marked with an orange background.

NOTE: Be careful when scheduling a repeating event as every time you schedule an event a new occurrence will be created. When dealing with repeating events ODIN will import data against the most recent occurrence of the event.

ODIN will use the current date and time when scheduling the events unless the user provides a different date and time. Users can schedule selected events or - if the events have already been scheduled - uncheck all events and schedule none.

Event name	Schedule? ☒	Date	Time	Forms
BasicQuestions	☒	2015-05-12	12:37	• CharBasicForm - v1.1 • CharBasicForm - v1.0
BloodPressure	☒	2015-05-12	12:37	• CharBPForm - v1.1 • CharBPForm - v1.0

3.4.5 (Optional) Upload a mapping file

Users can upload a previously created mapping file to skip the manual mapping process. This step is optional. If the user doesn't have a mapping file they can continue to define the CRF versions. Please find the detailed information about the mapping files in chapter 3.5 - Mapping files.

The screenshot shows the OpenClinica Data Importer web application. At the top is a blue header with the text "OpenClinica Data Importer web application". Below this is a navigation bar with links: "Home", "Profile", and "Templates". On the right side of the navigation bar, it says "Logged in as: ch686 (Logout)". Below the navigation bar is a breadcrumb trail: "Select a study > Upload data file > Validate data file > Import subjects > **Schedule events** > Upload mapping file > Define CRF versions > Mapping > Create XML > Import". The main content area is a light yellow box containing two buttons: "Upload a mapping file" (with a plus icon) and "Continue to CRF definitions" (with a right arrow icon), separated by the word "or". At the bottom of the page is a dark blue footer with the text "ODIN Beta - ver 0.8 Developed by Csaba Halmagyi@RDCIT".

3.4.6 Define CRF versions

Users can define the CRF versions they would like to import data against. All the events with all the assigned CRF versions will be displayed here. Unchecking forms/items in this phase will prevent those items from being used during the mapping process. Untick all unnecessary forms

Unchecking the form will automatically uncheck all the items.

The screenshot shows the "Define CRF versions" interface. It has a table with four columns: "Events", "Default CRF for the Event", "Check", "Version of CRF to use for import", and "Items in study".

Events	Default CRF for the Event	Check	Version of CRF to use for import	Items in study
BasicQuestions	CharBasicForm - v1.1	☒	CharBasicForm - v1.1	☒ GenHealth ☒ Visit_GP ☒ Have_Asthma ☒ Comments ☒ PrevIncidents ☒ IncidentCode
BloodPressure	CharBPForm - v1.1	☒	CharBPForm - v1.1	☒ Systolic ☒ Diastolic ☒ HeartRate

At the bottom of the interface is a button labeled "Continue to mapping!".

3.4.7 Mapping: assign the csv headers to CRF items

The mapping module will display all the OpenClinica forms and items the user selected in the previous step on the left side. On the right side there are the .csv data file headers. Users can assign the csv columns to the OpenClinica items by dragging and dropping the headers.

The screenshot displays the mapping module interface. On the left, under the heading "CRF items", there are two sections. The first section, "BasicQuestionsCharBasicForm - v1.1", lists items: GenHealth, Visit_GP, Have_Asthma, Comments, PrevIncidents, and IncidentCode. The second section, "BloodPressureCharBPForm - v1.1", lists items: Systolic, Diastolic, and HeartRate. Each item has an adjacent empty box for mapping. On the right, under the heading "Headers from csv", there is a list of headers: GeneralHealth, GP visits, HaveAsthma, Comments, Incidents, ICD10 code, Systolic, and Diastolic. Each header is enclosed in a box. At the bottom left, there is a checkbox labeled "Skip empty cells in datafile" which is checked, and a button labeled "Create ODM XML!".

Users can remove the associations by dragging the associated item and dropping it back to the right. If a mapping file was uploaded before defining the CRF versions the manual association can be skipped, but the associations from the mapping file cannot be overwritten manually.

After finishing the associations the ODM XML file can be created. There must be at least one header assigned to an item in order to create the XML file.

CRF items	Associated item
BasicQuestions BasicQuestionsCharBasicForm - v1.1	
GenHealth	GeneralHealth
Visit_GP	GP visits
Have_Asthma	HaveAsthma
Comments	Comments
PrevIncidents	Incidents
IncidentCode	ICD10 code
BloodPressure BloodPressureCharBPForm - v1.1	
Systolic	
Diastolic	
HeartRate	

Headers from csv
 Systolic
 Diastolic

☒ Skip empty cells in datafile

There is an extra checkbox on the bottom of this screen. ODIN will skip all the empty cells in the data file by default (these data points will be skipped during the XML creation process). If users untick this checkbox they will force ODIN to insert an empty value for data points where no data was found. This option can be useful when they would like to overwrite a previously entered/imported value with an empty value. When users click on “Create ODM XML” button the mapping rules will be saved and stored in a mapping file. These files can be downloaded from the user’s Profile menu.

3.4.8 Create the CDISC ODM XML

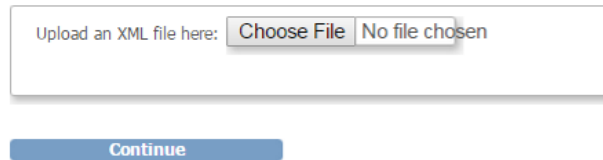
ODIN will create a CDISC ODM XML file based on the mapping rules created previously. This file can be downloaded by clicking on the button as shown below. If users are allowed to import directly to this OpenClinica instance the “Import data from this XML” button will be shown, but we strongly recommend to disable that option. Instead of importing directly to OC, download the XML file and use the OpenClinica importing facilities. The OpenClinica import

XML import file created successfully.

Submit Data	
Subject Matrix	Schedule Event
Add Subject	View Events
Notes & Discrepancies	Import Data
Monitor and Manage Data	

task will validate the xml data prior to the import and provide error messages if any errors were found. If an error was found the user is prompted to upload a new xml file at the bottom.

Upload an xml file that contains CRF data. If your CRF has calculated value fields, you will have to go in and save each section. OpenClinica only calculates values on a manual save.



By clicking on the “Start new import” button ODIN will reset the current import session, redirect the user to the Main menu and generate a new session id for a new import. If a user returns to the Main menu without resetting the import session and start a new import, all xml and mapping rules will be overwritten. Please don’t use the web browsers back button to go back to the previous page as ODIN may lose some critical information.

3.4.9 Import

If ODIN was set up to allow users to import data directly into OpenClinica, the application will create a webservice request using the currently created CDISC ODM XML.

3.5 Mapping files

Every time the user clicks on the “Create ODM XML” button a mapping file will be created to store the association rules. These files contain three columns. The first column is for storing the full OID reference to an item in OpenClinica. The OIDs are separated by double hashes.

Example:

SE_BASICQUESTIONS##F_CHARBASICFOR_V11##IG_CHARB_BASICQUESTIONS##I_CHARB_GENHEALTH

The second column contains the event name, the form name and the item name.

The third column contains the csv datafile header name associated to the item.

Once a mapping file has been created it can be reused if the user imports data against the same items (overwriting previously imported data or importing data for new subjects). The previously saved mapping files can be downloaded by visiting the user’s profile page.

User	ch686
First name	Csaba
Last name	Halmagyi
Email	ch686@medschl.cam.ac.uk
Current Import ID	556461ce606fb

Mapping file name	Date created	Time created	XML Data file
map_555644350ed8f_csv	2015-May-15	20:13	import_555644350ed8f.xml
map_555484bd3bc75_csv	2015-May-14	12:24	import_555484bd3bc75.xml
map_5551ff112c55e_csv	2015-May-12	14:44	import_5551ff112c55e.xml
map_554a01941e113_csv	2015-May-06	13:02	import_554a01941e113.xml

[Go back](#)

3.7 Errors and problems

The most common errors and problems are the following (these errors will (at this time) not be filtered out by ODIN):

- The data in your csv data file is stored in a wrong format (e.g. dates).

IG_BASIC_DIAGNOSIS (Repeat Key 1)	
I_BASIC_DIAG_DATE	16/05/2008 You have a date value which is not in ISO 8601 format at the OID I_BASIC_DIAG_DATE. Check it and try again.
IG_BASIC_DEMOGRAPHICS (Repeat Key 1)	

- The data loaded from the .csv file violates OC response set (e.g. the input is expected to be 1 or 2 and the user wanted to import 3)

IG_CHARB_BASICQUESTIONS (Repeat Key 1)

I_CHARB_HAVE_ASTMHA

3

This is not in the correct response set.

- The user uses special character encoding which is not supported by OpenClinica (the ODM XML will be invalid).
- The user creates an invalid XML due to mismatching the OC items and the csv headers.

3.8 Useful links

Please visit www.rdcit.org for more information about the RDCIT tools.