

# OpenClinica Data Importer

## Software Design Document and User Guide

### Document History

Version	Date	Description	Authors
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# 1 INTRODUCTION

## **1.1 Product Identification**

This document contains the Software Design Specifications for the OpenClinica generic data importer.

## **1.2 Purpose of the Document**

The purpose of this document is to provide the detailed software design and the user guide.

## **1.3 Scope of the Document**

The scope of the body of this document is to describe the implementation of “OCDatImporter” program. Other aspects related to SPSS, MS Excel and OpenClinica can be found in SPSS, Excel and OpenClinica documents.

## **1.4 Intended Audience**

Open Clinica users, data managers.

## **1.5 References**

Microsoft .NET documentation, OpenClinica documents, PostGreSQL documents.

## 2 GENERAL DESCRIPTION

### 2.1 *Product Perspective*

This product will make it possible to convert a study data file into an OpenClinica study.

### 2.2 *Product Availability*

The product is available in May 2010.

### 2.3 *Principle Product Functionality*

This application is based on reading a study file and converting it to a OpenClinica study.

### 2.4 *General Constraints*

This product requires Microsoft .NET Framework version 3.5 distributable Package.  
It is included in Windows Vista and Windows 7.

Otherwise, it is possible to download this from the following site:

<http://msdn.microsoft.com/downloads/>

The program is not yet available under other operating systems.

**CAUTION: This program introduces a complex procedure of importing legacy data in Open Clinica. Usage of this program requires expertise level knowledge of Open Clinica and the Postgres database. Furthermore administrator privileges will be needed at the database server side in order to run the database scripts to create subjects and events. Please make sure you read this document carefully before you start using the application.**

## 3 USER GUIDE

This section describes how to use this application.

### 3.1 *Installation*

To install this program, create a directory, such as C:\OCDatImporter.  
Copy the executable "OCDatImporter.exe" and "OCDatImporter.pdf" to this directory.  
Open Windows explorer and double click to start the program.

You should see the following form:

## OCDatImporter

OCDatImporter - Provided by VU Medical Center, dept. of Pathology, Amsterdam

File Help

**OCDatImporter Version 2.0**

Enter Input files: OC MetaData file (XML) and Study Data file (TXT), separated by a ';', or use 'Browse' button

OC TARGET: Study Event CRF Group Item

Date format in study items: --select-- Default sex of subjects: f Gender Code for m: Gender Code for f: [Match columns](#)

Split the ODM file where each contains the following number of subjects (0 = no split) 0 Location: Amsterdam Check duplicate study subject ID's ☐

	Study Data Column	OC Target Item	Study Subject ID?	Date?	Subject Sex?	Subject Person ID?	Subject Date of Birth?	Subject start date?	CopyTarget
*			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Replace string pairs

// Enter replace couples here  
 // Everything after a // (like this line) is a comment  
 // Format is: STUDYDATACOLUMN-ITEM;old;new. Example:  
 // MYDATACOL1;Amsterdam;A'dam  
 // MYDATACOL2;1;M

Progress

### 3.2 First step: Convert study to a tab delimited text file.

1- Create a directory, for example C:\MyData.

2- Start SPSS, Excel or another program to convert the study file to a tab delimited text file, named for example "ThePatientDataFile.txt".

The file should look like the following:

bonr	lftd	gr	cyt1_dat	hvp_01	hvp_06	hvp_18	cyt1_3	cyt06_3	cyt18_3	v16a11	v18a11	cin2	cin3	hist_pro
B000-00372	60	i	26-Jan-2000	1	3	3	0	3	3	0	0	1.00	1.00	4.00
B000-01146	39	i	24-Feb-2000	1	3	3	0	3	3	1	0	1.00	1.00	4.00
B000-01248	39	i	25-Feb-2000	1	3	3	0	3	3	0	0	1.00	1.00	4.00
B000-01583	33	i	14-Mar-2000	1	3	3	0	3	3	1	0	1.00	1.00	4.00
B000-01701	40	i	15-Mar-2000	1	3	3	0	0	3	1	0	0.00	0.00	6.00
B000-03297	54	i	13-Apr-2000	1	3	3	0	0	3	1	0	1.00	0.00	5.00
B000-04043	45	i	26-Apr-2000	1	3	3	0	3	3	1	0	1.00	1.00	4.00
B000-06123	43	i	09-Jun-2000	1	3	3	0	1	3	1	0	1.00	1.00	4.00
B000-06458	31	i	19-Jun-2000	1	3	3	0	3	3	0	0	1.00	1.00	4.00
B000-06893	34	i	29-Jul-2000	1	3	3	0	0	2	0	0	0.00	0.00	6.00
B000-07025	34	i	04-Jul-2000	1	3	3	0	2	2	1	0	1.00	0.00	5.00
B000-07070	34	i	05-Jul-2000	1	3	3	0	1	3	0	0	1.00	1.00	4.00
B000-07155	29	i	07-Jul-2000	1	3	3	0	3	3	0	0	1.00	1.00	4.00
B000-07423	54	i	17-Jul-2000	1	1	2	0	2	1	0	0	0.00	0.00	11.00
B000-07589	40	i	21-Jul-2000	1	3	3	0	3	3	1	0	1.00	1.00	4.00
B000-07816	54	i	03-Aug-2000	1	3	3	0	3	3	0	1	1.00	1.00	4.00
B000-07817	39	i	03-Aug-2000	1	3	3	0	2	2	0	0	0.00	0.00	6.00
B000-07829	32	i	03-Aug-2000	1	3	3	0	3	3	1	0	1.00	1.00	4.00
B000-07917	31	i	14-Aug-2000	1	3	3	0	3	3	1	0	1.00	1.00	4.00
B000-08092	32	i	25-Aug-2000	1	3	3	0	0	1	0	0	0.00	0.00	6.00
B000-08426	36	i	12-Sep-2000	1	3	3	0	0	3	0	0	1.00	1.00	4.00
B000-08785	55	i	20-Sep-2000	1	3	3	0	0	3	1	0	1.00	1.00	4.00
B000-09086	35	i	06-Oct-2000	1	3	3	0	3	3	1	0	1.00	1.00	4.00
B000-10281	35	i	19-Oct-2000	1	3	3	0	2	2	0	0	1.00	0.00	5.00
B000-10349	60	i	19-Oct-2000	1	3	3	0	3	3	0	0	1.00	1.00	4.00
B000-10367	30	i	20-Oct-2000	1	1	1	0	2	2	0	0	0.00	0.00	7.00
B000-10596	35	i	26-Oct-2000	1	3	3	0	2	3	1	0	1.00	1.00	4.00
B000-10607	29	i	26-Oct-2000	1	3	3	0	2	2	0	0	0.00	0.00	11.00
B000-10704	35	i	02-Nov-2000	1	3	3	0	3	3	0	0	1.00	1.00	4.00
B000-10820	35	i	02-Nov-2000	1	3	3	0	3	3	1	0	1.00	1.00	4.00
B000-10952	30	i	10-Nov-2000	1	3	3	0	3	3	1	0	1.00	1.00	4.00
B000-11206	30	i	10-Nov-2000	1	3	3	0	0	2	0	0	1.00	0.00	5.00
B000-11540	30	i	16-Nov-2000	1	3	3	0	0	3	0	0	1.00	1.00	4.00
B000-11598	30	i	17-Nov-2000	1	3	3	0	3	3	1	0	1.00	1.00	4.00
B000-11642	60	i	24-Nov-2000	1	1	1	0	1	0	0	0	0.00	0.00	11.00

3- Copy this file to C:\MytData.

### 3.3 Create the Study, events and CRF(s) in OpenClinica.

To do this, start OpenClinica, login as Datamanager, Create a study named for example "S\_CAIRO\_1", create the necessary events and CRF's with items which matches with the items for the file generated in section 3.2. For more on using OpenClinica, refer to OpenClinica documents.

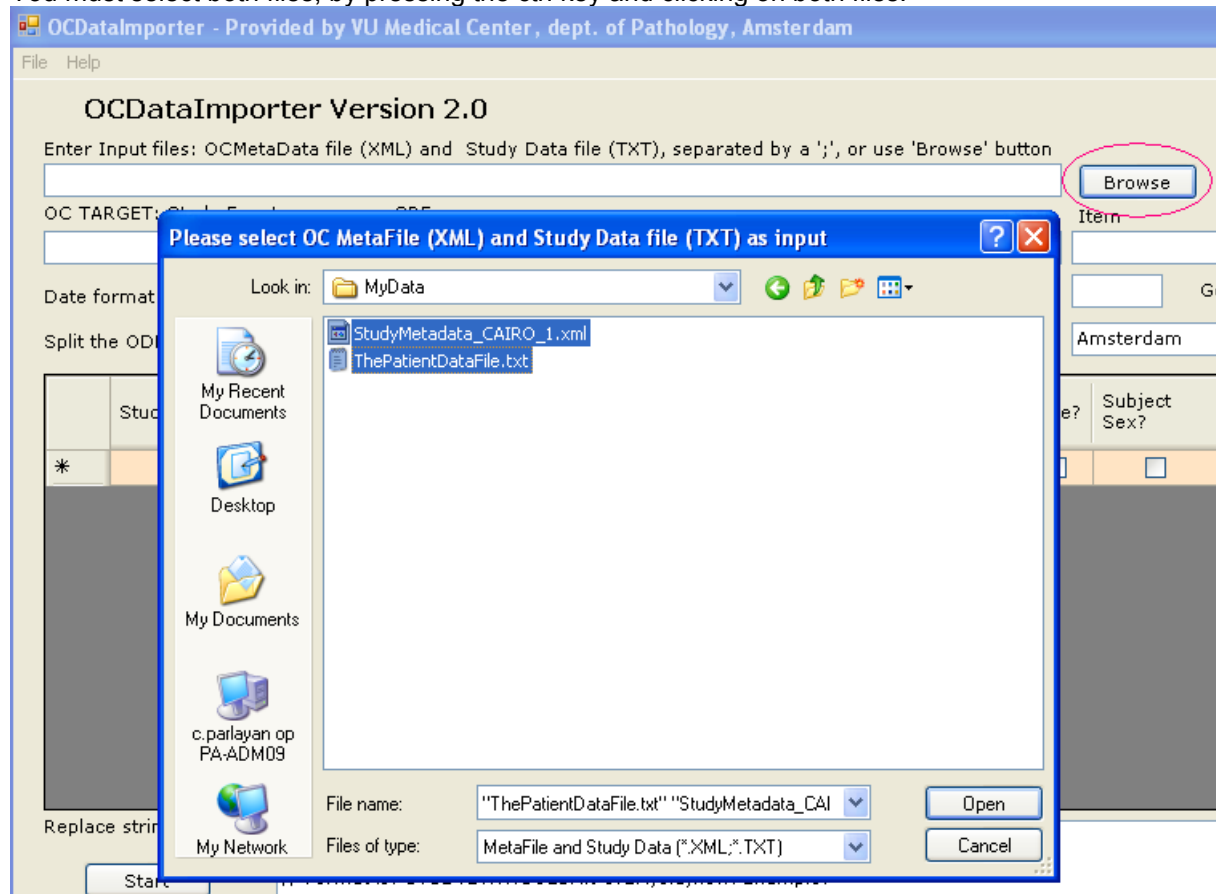
### 3.4 Create OpenClinica Meta Data File using OpenClinica.

Once the OpenClinica objects are created, generate the meta data file.  
View the study and Click "here" of the sentence "Download all of the OID's needed for data import and rules". Give the file a name, for example "StudyMetadata\_CAIRO\_1.xml" and save the file in C:\MyData.

### 3.5 Read the input files in "OCDatImporter"

Hit the "browse" button and select the files that are generated: The meta file and the tab delimited data file.

You must select both files, by pressing the ctrl key and clicking on both files.



Now hit the "read input files" button.

The program will check if the number of columns in the data file is the same with the items in the Meta file. If so, an automatic matching is done, but mostly there are more than one CRF's defined for one patient data file so the column matching will be mostly done manually.

The ideal situation is, OC data items and the source file columns all have same names. For example if the source data column name is "Gender" and the OC item is also named "Gender" an automatic matching can be made.

### 3.6 Matching data columns and OpenClinica Items

To match the columns in case there are more than one study event and/or CRF's, you can choose the event, group and the CRF and then hit "Match columns" link. The Items combobox should be left as – select--. This will check for similar names and match them.

If the names are not similar or the OC item does not exist in the selected CRF (because it exists in another CRF or even doesn't exist at all) matching can be done manually. The program will issue a message indicating this. To see the items that are NOT matched, see the Progress textbox as shown below:

When no matching could be made, the program will display the "study data columns" of the grid, but it will leave the "OC Target Item" blank or fill it as "none". This can be filled in by using the "CopyTarget" link. To use this link, first chose the target item using the Study event, CRF, Group and Items combo boxes, then hit the CopyTarget of the row which has to be matched with that item.

Suppose you want to match "CAIRO\_N" with I\_CAIRO\_REASON\_NOT\_USED\_BY\_JOSIEN\_H

Use the combo boxes so that the above item appears in the combo boxes and hit "CopyTarget" of the row of "CAIRO\_N".

## OCDatImporter

OCDatImporter - Provided by VU Medical Center, dept. of Pathology, Amsterdam

File Help

**OCDatImporter Version 2.0**

Enter Input files: OC MetaData file (XML) and Study Data file (TXT), separated by a ';', or use 'Browse' button  
 C:\MyData\StudyMetadata\_CAIRO\_1.xml;C:\MyData\ThePatientDataFile.txt

OC TARGET: Study Event CRF Group Item  
 SE\_CAIRO\_EVENT F\_CAIRO\_GEN\_IN\_V12 IG\_CAIRO\_UNGROUPED I\_CAIRO\_REASON\_NOT\_USED\_BY\_JOSIEN\_H

Date format in study items --select-- Default sex of subjects f Gender Code for m: Gender Code for f: Match columns

Split the ODM file where each contains the following number of subjects (0 = no split) 0 Location: Amsterdam Check duplicate study subject ID's ☐

Study Data Column	OC Target Item	Study Subject ID?	Date?	Subject Sex?	Subject Person ID?	Subject Date of Birth?	Subject start date?	CopyTarget
CAIRO_Site_of_primary_tumor	none	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CopyTarget
CAIRO_T	none	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CopyTarget
CAIRO_T_JH	none	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CopyTarget
CAIRO_TumorDiameter	none	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CopyTarget
CAIRO_TumorDiameterNULL	none	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CopyTarget
CAIRO_N	none	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CopyTarget
CAIRO_N_JH	none	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CopyTarget
CAIRO_NumberLymphNodesRemoved	none	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CopyTarget
CAIRO_NumberLymphNodesRemov...	none	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CopyTarget
CAIRO_NumberLymphNodesPositive	none	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CopyTarget

The program will copy the target item into the “OC target Item” field.

OCDatImporter - Provided by VU Medical Center, dept. of Pathology, Amsterdam

File Help

**OCDatImporter Version 2.0**

Enter Input files: OC MetaData file (XML) and Study Data file (TXT), separated by a ';', or use 'Browse' button  
 C:\MyData\StudyMetadata\_CAIRO\_1.xml;C:\MyData\ThePatientDataFile.txt

OC TARGET: Study Event CRF Group Item  
 SE\_CAIRO\_EVENT F\_CAIRO\_GEN\_IN\_V12 IG\_CAIRO\_UNGROUPED I\_CAIRO\_REASON\_NOT\_USED\_BY\_JOSIEN\_H

Date format in study items --select-- Default sex of subjects f Gender Code for m: Gender Code for f: Match columns

Split the ODM file where each contains the following number of subjects (0 = no split) 0 Location: Amsterdam Check duplicate study subject ID's ☐

Study Data Column	OC Target Item	Study Subject ID?	Date?	Subject Sex?	Subject Person ID?	Subject Date of Birth?	Subject start date?	CopyTarget
CAIRO_Site_of_primary_tumor	none	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CopyTarget
CAIRO_T	none	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CopyTarget
CAIRO_T_JH	none	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CopyTarget
CAIRO_TumorDiameter	none	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CopyTarget
CAIRO_TumorDiameterNULL	none	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CopyTarget
CAIRO_N	SE_CAIRO_EVENT.F_CAIRO_GEN_IN_V12.IG_CAIRO_UNGROUPED.I_CAIRO_REASON_NOT_USED_BY_JOSIEN_H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CopyTarget
CAIRO_N_JH	none	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CopyTarget
CAIRO_NumberLymphNodesRemoved	none	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CopyTarget
CAIRO_NumberLymphNodesRemov...	none	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CopyTarget

### 3.7 Indicating study subject id, Subject sex, subject person's id, subject start date

The program needs to know which data column is the subject id. Without a subject id, the process can't be made. So there has to be one (and only one) subject id checked in the whole grid. This will be used to create subject records and relate the CRF data with this subject.

There are also other items needed to create the subject like subject sex, subject person's id, subject date of birth and subject start date. These can be indicated with the related checkboxes as shown below.

To convert the dates into ODM format, you must indicate that a field is a date field, by checking the “Date?” checkbox. If “date” appears in the item name, this will be automatically checked. More than one date item may occur.



## OCDataImporter

OCDataImporter - Provided by VU Medical Center, dept. of Pathology, Amsterdam

File Help

OCDataImporter Version 2.0

Enter Input files: OC MetaData file (XML) and Study Data file (TXT), separated by a ';', or use 'Browse' button  
 C:\MyData\StudyMetadata\_CAIRO\_1.xml;C:\MyData\ThePatientDataFile.txt

Browse Read Input Files

OC TARGET: Study Event CRF Group Item  
 SE\_CAIRO\_EVENT F\_CAIRO\_GEN\_IN\_V12 IG\_CAIRO\_UNGROUPED I\_CAIRO\_REASON\_NOT\_USED\_BY\_JOSIEN\_H

Date format in study items --select-- Default sex of subjects f Gender Code for m: Gender Code for f: Match

Split the ODM file where each contains the following number of subjects (0 = no split) 0 Location: Amsterdam Check duplicate study subjects

	Study Data Column	OC Target Item	Study Subject ID?	Date?	Subject Sex?	Subject Person ID?	Subject Date of Birth?	Subject start date?	CopyTarget
▶	CAIRO_Patient_ID	SE_CAIRO_EVENT.F_CAIRO_G...	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CopyTarget
	CAIRO_used_in_analyses_J...	none	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CopyTarget
	CAIRO_GEO_number	SE_CAIRO_EVENT.F_CAIRO_G...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CopyTarget
	CAIRO_GEO_sample_name	SE_CAIRO_EVENT.F_CAIRO_G...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CopyTarget
	CAIRO_reason_not_used_b...	none	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CopyTarget
	CAIRO_CGH_info	SE_CAIRO_EVENT.F_CAIRO_G...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CopyTarget
	CAIRO_Eligible	SE_CAIRO_EVENT.F_CAIRO_G...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CopyTarget
	CAIRO_Date_of_birth	SE_CAIRO_EVENT.F_CAIRO_G...	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	CopyTarget
	CAIRO_Gender	SE_CAIRO_EVENT.F_CAIRO_G...	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CopyTarget
	CAIRO_WHO_performance...	SE_CAIRO_EVENT.F_CAIRO_G...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CopyTarget

### 3.8 Specifying date format

You can optionally specify the format of dates in the data file by using the "Date format in study items" combo box. The dates in OC Import XML file **must** be in YYYY-MM-DD format. The program takes care of converting the dates from the format of your choice to OC format. If you do not want any conversion to take place, leave the selected item as "--select--", but in this case either you must be sure that all dates are in ODM format YYYY-MM-DD or there are no dates at all in your data file.

Date format in study items --select--

Split the ODM file where each contains the following number of subjects (0 = no split) 0

Location: Amsterdam

dd-mmm-yyyy  
dd-MMM-yyyy  
dd-mm-yyyy

### 3.9 Specifying gender codes

The codes for male and female in OpenClinica has to be "m" and "f" respectively. If this appears otherwise in your data file you can indicate this by using the appropriate textboxes as indicated below. If male is coded as 1 and female as 2 in your data file, below coding will make the proper translation.

Default sex of subjects f

Gender Code for m: 1 Gender Code for f: 2

g number of subjects (0 = no split) 0 Location: Amsterdam Check duplicate study subjects

If there is no gender code in your file and all participants are female, then you can leave the Gender code fields blank and select "f" as default sex of subjects. If the gender code fields are filled, default sex will be ignored.

### 3.10 Specifying text to replace with other text or delete

You can optionally define text to be replaced or removed, when creating OC study from data file. Use "Replace string pairs" text box for this. Format is: STUDYDATACOLUMNITEM;oldtext;newtext.

Examples:

1- Change all "Amsterdam" to "A'dam" :  
City;Amsterdam;A'dam

2- In the original file gender is coded as 1 and 2, we want to create the OC study with M a and F  
Gender;1;M  
Gender;2;F

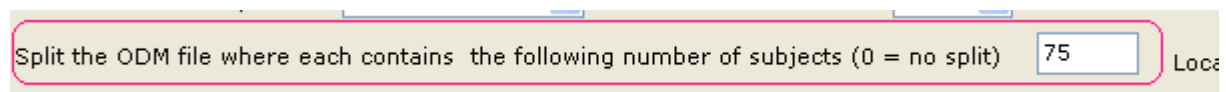
3- Use <null> to replace with null: We want to get rid of .00 in amount field; so 3.00 must be treated as 3  
Amount;.00;<null>

4- The ';' is the separator but if desired this can be changed, to change the separator, use  
SEPARATOR command:  
SEPARATOR=\$  
Amount\$.00\$<null>

5- Use ALL to apply changes to all fields: You want to delete all (not just the field amount) .00  
ALL;.00;<null>

### 3.11 Splitting the ODM file

Open Clinica may not be able to handle ODM files with more than 75 subject-data in one ODM file when the user interface is used for uploading. It is recommended to split the ODM file into pieces which will contain no more than a specified number of subject data. In version 3.1.2 it was able to handle 75 subject data in one file. When you enter 75, several files will be generated with 75 subject-data each, named "DataImport\_1, ...\_2, ...\_3, etc.  
Enter 0 if no splitting is desired. (We hope that there will be no splitting needed in the future versions)



Split the ODM file where each contains the following number of subjects (0 = no split)  Location

### 3.12 Specifying the location

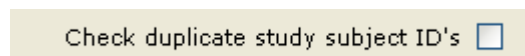
It is possible to give the location name to be used in event subjects.



Location:

### 3.13 Specifying if duplicate key check is needed

If your data file contains only one row for each subject and the subject id's must be unique, this program can check that and issue an error message if that fails. Use the checkbox below, to perform this check.



Check duplicate study subject ID's ☐

### 3.14 Starting the conversion

When all above choices from 3.1 to 3.13 are made, the program is ready to process the data and generate the files needed to upload to OpenClinica. Hit the start button, as shown below.


## OCDatImporter

Study Data Column	OC Target Item	Study Subject ID?	Date?	Subject Sex?	Subject Person ID?	Subject Date of Birth?	Subject start date?	CopyTarget
CAIRO_Patient_ID	SE_CAIRO_EVENT.F_CAIRO_G...	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<a href="#">CopyTarget</a>
CAIRO_used_in_analyses_J...	none	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<a href="#">CopyTarget</a>
CAIRO_GEO_number	SE_CAIRO_EVENT.F_CAIRO_G...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<a href="#">CopyTarget</a>
CAIRO_GEO_sample_name	SE_CAIRO_EVENT.F_CAIRO_G...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<a href="#">CopyTarget</a>
CAIRO_reason_not_used_b...	none	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<a href="#">CopyTarget</a>
CAIRO_CGH_info	SE_CAIRO_EVENT.F_CAIRO_G...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<a href="#">CopyTarget</a>
CAIRO_Eligible	SE_CAIRO_EVENT.F_CAIRO_G...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<a href="#">CopyTarget</a>
CAIRO_Date_of_birth	SE_CAIRO_EVENT.F_CAIRO_G...	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<a href="#">CopyTarget</a>
CAIRO_Gender	SE_CAIRO_EVENT.F_CAIRO_G...	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<a href="#">CopyTarget</a>
CAIRO_WHO_performance_...	SE_CAIRO_EVENT.F_CAIRO_G...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<a href="#">CopyTarget</a>

Replace string pairs

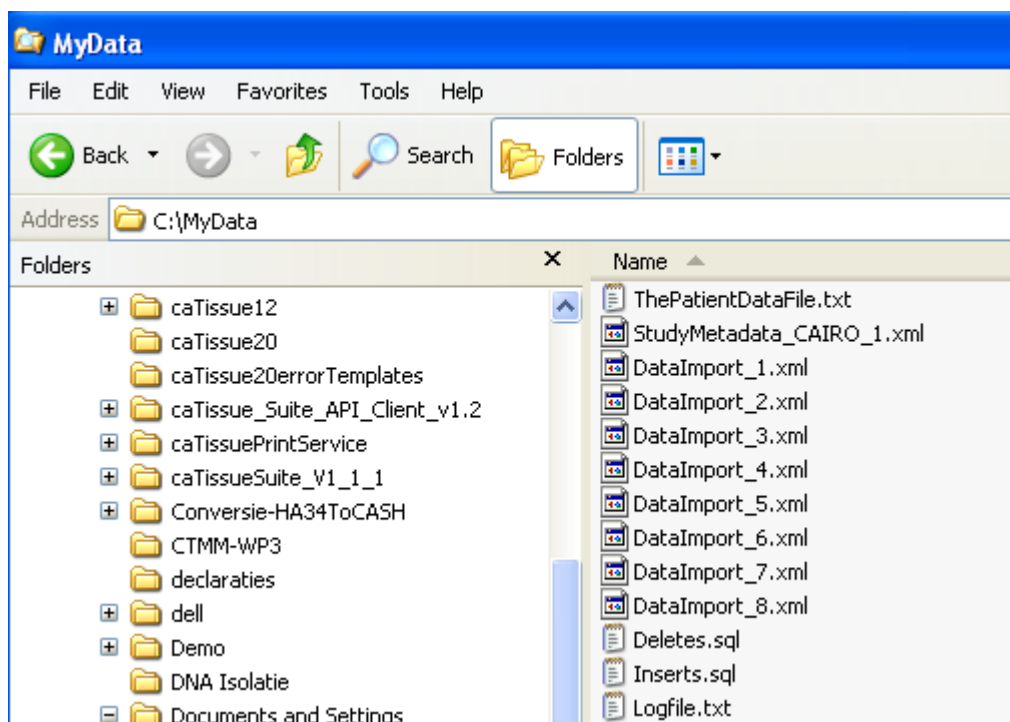
// Enter replace couples here  
 // Everthing after a // (like this line) is a comment  
 // Format is: STUDYDATACOLUMN-ITEM;old;new. Example:  
 // MYDATACOL1;Amsterdam;A'dam  
 // MYDATACOL2;1;M

Normally it would result in the following:

Progress 

The following items in the Items combobox could not be matched with any of the Study Items:  
 I\_CAIRO\_REASON\_NOT\_USED\_BY\_JOSIEN\_H  
 I\_CAIRO\_USED\_IN\_ANALYSES\_JOSIEN\_HAA  
 Selected Item = I\_CAIRO\_REASON\_NOT\_USED\_BY\_JOSIEN\_H

Data file is: C:\MyData\ThePatientDataFile.txt, delimited by:                      Number of items per line: 73  
 Creating files: DataImport.xml, Inserts.sql and Deletes.sql in directory C:\MyData. This may take several minutes...  
 Finished successfully Total: 8 ODM files.



The program can issue a number of error messages while running this process. See appendix for the list of possible things that can go wrong.

### 3.15 Creating subjects, study\_subjects and study\_events in PostgreSQL using "Inserts.sql".

The file "Inserts.sql" will be used to create subject, study\_subject and study\_event rows in Postgres. It contains insert statements for those three tables.

For example, for the first line of the study data:

NIJM_CAIRO_CRC_002	0	No distant metastasis, number of affected									
organs is 0 (array CGH data is available)	0	5-mrt-1942	1	1	1						
13-jan-2003	60	1	4	-1	-1	1	-1	1	-1	0	
-1	-1	0	1	3	0	-1	-1	-1	-1	0	
-3	-1	-1	-1	0	1	1	0	18		-1	
1	435	-1	1	0		-1	-1	435		-1	
1	0	-1	-1	435		-1	1		1454	1	
1	1	0									

The following will be created:

```

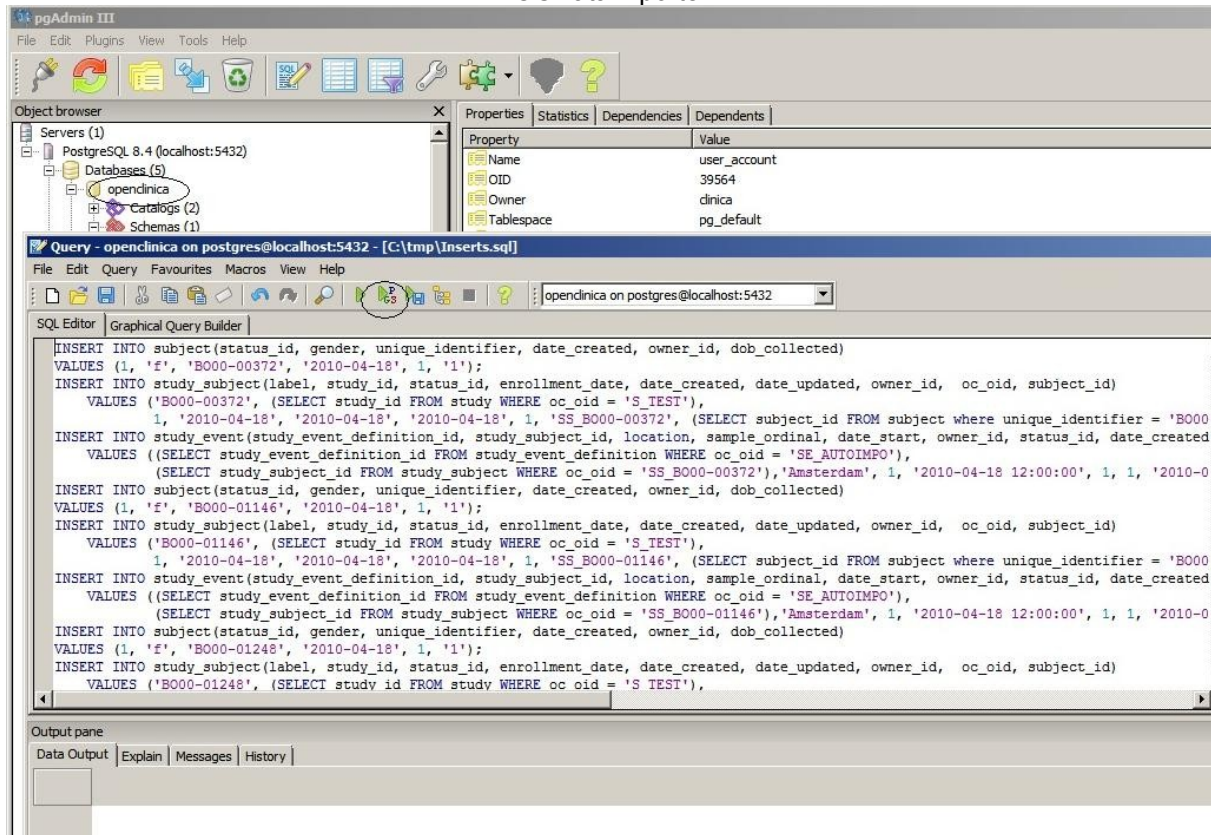
INSERT INTO subject(status_id, gender, unique_identifier, date_created, owner_id, dob_collected,
date_of_birth)
VALUES (1, 'm', 'NIJM_CAIRO_CRC_002', '2012-11-05', 1, '1', '1942-03-05');
INSERT INTO study_subject(label, study_id, status_id, enrollment_date, date_created, date_updated,
owner_id, oc_oid, subject_id)
VALUES ('NIJM_CAIRO_CRC_002', (SELECT study_id FROM study WHERE oc_oid =
'S_CAIRO'),
1, '2012-11-05', '2012-11-05', '2012-11-05', 1, 'SS_NIJM_CAIRO_CRC_002', (SELECT
subject_id FROM subject where unique_identifier = 'NIJM_CAIRO_CRC_002'));
INSERT INTO study_event(study_event_definition_id, study_subject_id, location, sample_ordinal,
date_start, owner_id, status_id, date_created, subject_event_status_id, start_time_flag,
end_time_flag)
VALUES ((SELECT study_event_definition_id FROM study_event_definition WHERE oc_oid =
'SE_CAIRO_EVENT'),
(SELECT study_subject_id FROM study_subject WHERE oc_oid =
'SS_NIJM_CAIRO_CRC_002'),'Amsterdam', 1, '2012-11-05 12:00:00', 1, 1, '2012-11-05', 3, '0', '0');

INSERT INTO subject(status_id, gender, unique_identifier, date_created, owner_id, dob_collected)
VALUES (1, 'f', 'BO00-00372', '2010-04-26', 1, '1');
INSERT INTO study_subject(label, study_id, status_id, enrollment_date, date_created, date_updated,
owner_id, oc_oid, subject_id)
VALUES ('BO00-00372', (SELECT study_id FROM study WHERE oc_oid = 'S_POBASCAM'),
1, '2010-04-26', '2010-04-26', '2010-04-26', 1, 'SS_BO00-00372', (SELECT subject_id FROM
subject where unique_identifier = 'BO00-00372'));
INSERT INTO study_event(study_event_definition_id, study_subject_id, location, sample_ordinal,
date_start, owner_id, status_id, date_created, subject_event_status_id, start_time_flag,
end_time_flag)
VALUES ((SELECT study_event_definition_id FROM study_event_definition WHERE oc_oid =
'SE_AUTOIMPO'),
(SELECT study_subject_id FROM study_subject WHERE oc_oid = 'SS_BO00-
00372'),'Amsterdam', 1, '2010-04-26 12:00:00', 1, 1, '2010-04-26', 3, '0', '0');

```

To run this SQL file, start PGAdmin at the OpenClinica database server, select the openclinica database, start Query tool from "Tools" pulldown menu, read "Inserts.sql" file and run this with "execute pgscript". See Postgres user manuals for more information on how this is made, if necessary. **CAUTION: Make sure the OpenClinica instance is NOT running at this time and don't forget to make a full backup of the database before you start!**

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When this is done, proceed with the following section.

*Note: Deletes.sql can be used to undo the above operation.*

### 3.16 Importing data to OpenClinica using "DataImport\_(n).xml".

The file DataImport\_(n).xml contains a fixed begin section + import statements for each line in the file created in section 3.2. + fixed end section.

```
<?xml version="1.0" encoding="UTF-8"?>
<ODM xmlns="http://www.cdisc.org/ns/odm/v1.3"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xsi:schemaLocation="http://www.cdisc.org/ns/odm/v1.3 ODM1-3.xsd"
ODMVersion="1.3" FileOID="1D20080412202420" FileType="Snapshot"
Description="First dataset for testing of ODM" CreationDateTime="2008-04-12T20:24:20" >
<ClinicalData StudyOID="S_VUMCDEPT" MetaDataVersionOID="v1.0.0">
  <SubjectData SubjectKey="SS_NIJM_CAIRO_CRC_002">
    <StudyEventData StudyEventOID="SE_CAIRO_EVENT" StudyEventRepeatKey="1">
      <FormData FormOID="F_CAIRO_GEN_IN_V12">
        <ItemGroupData ItemGroupOID="IG_CAIRO_UNGROUPED" TransactionType="Insert" >
          <ItemData ItemOID="I_CAIRO_AGE" Value="60" />
          <ItemData ItemOID="I_CAIRO_DATE_OF_BIRTH" Value="1942-03-05" />
          <ItemData ItemOID="I_CAIRO_DATE_OF_RANDOMISATION" Value="2003-01-13" />
          <ItemData ItemOID="I_CAIRO_ELIGIBLE" Value="0" />
          <ItemData ItemOID="I_CAIRO_GENDER" Value="1" />
          <ItemData ItemOID="I_CAIRO_PATIENT_ID" Value="NIJM_CAIRO_CRC_002" />
          <ItemData ItemOID="I_CAIRO_WHO_PERFORMANCE_STATUS" Value="1" />
        </ItemGroupData>
      </FormData>
    </StudyEventData>
  </SubjectData>
```

....

```
....
</ClinicalData>
</ODM>
```

The above subject data corresponds with the first line of the data file:

```
NIJM_CAIRO_CRC_002      0      No distant metastasis, number of affected
organs is 0 (array CGH data is available)      0      5-mrt-1942      1      1      1
13-jan-2003      60      1      4      -1      -1      1      -1      1
-1      -1      -1      0      1      3      0      -1      -1      -1      0
-3      -1      -1      -1      0      1      1      0      18      -1
1      435      -1      1      0      -1      -1      435      1454      1
1      0      -1      -1      435      -1      1      1454      1
1      1      0
```

Depending on the given split factor (section 3.11), a number of DataImport\_(n).xml files will be created.

When this file is (these files are) uploaded in OpenClinica, the data conversion process will be completed.

To do this, start OpenClinica, click ok “Import Data” of the tasks menu.

The screenshot shows the OpenClinica web interface for the study 'POBASCAM\_demo'. The user is logged in as 'cparlayan (Data Manager)'. The 'Tasks' menu is open, and the 'Import Data' option is highlighted. The main content area shows a 'Welcome to POBASCAM\_demo' message and a table of 'Notes & Discrepancies Assigned to Me.'.

Site	Enrolled	Expected Enrollment	Percentage
VUmc, dept of Pathology	3006	3006	100%

Event Status	# of Events	Percentage
scheduled	0	0%
data entry started	4	0%
completed	3002	100%
signed	0	0%
locked	0	0%
skipped	0	0%
stopped	0	0%

In the next screen, you can enter the path to DataImport\_(n).xml:

The screenshot shows the 'Import CRF Data' screen in the OpenClinica web interface. The user is logged in as 'cparlayan (Data Manager)'. The screen displays instructions for uploading CRF data and a form to enter the XML file path.

XML File To Upload:





```

                                OCDataImporter
<ItemData ItemOID="I_ADVE_ITEM_BEFORE" Value="bef2" />
</ItemGroupData>
<ItemGroupData ItemGroupOID="IG_ADVE_ADVERSEEVENTS_7407"
ItemGroupRepeatKey="1" TransactionType="Insert" >
    <ItemData ItemOID="I_ADVE_ADVERSE_EVENT_678" Value="ae21" />
    <ItemData ItemOID="I_ADVE_DATE_ONSET_7692" Value="1960-01-02" />
</ItemGroupData>
    <ItemGroupData ItemGroupOID="IG_ADVE_ADVERSEEVENTS_7407"
ItemGroupRepeatKey="2" TransactionType="Insert" >
    <ItemData ItemOID="I_ADVE_ADVERSE_EVENT_678" Value="ae22" />
    <ItemData ItemOID="I_ADVE_DATE_ONSET_7692" Value="1960-02-02" />
</ItemGroupData>
    <ItemGroupData ItemGroupOID="IG_ADVE_ADVERSEEVENTS_7407"
ItemGroupRepeatKey="3" TransactionType="Insert" >
    <ItemData ItemOID="I_ADVE_ADVERSE_EVENT_678" Value="ae23" />
    <ItemData ItemOID="I_ADVE_DATE_ONSET_7692" Value="1960-03-02" />
</ItemGroupData>

```

All repeating data columns should be mapped with the same OC item, as to be seen below.

Study Data Column	OC Target Item
subject_id	Use link button 'CopyTarget' to fill this cell with the selected target item
item_before_E1	SE_TEST_MEDICATIE_GROUPS_REPEAT.F_ADVE_6538_V11.IG_ADVE_UNGROUPED_4947.I_ADVE_ITEM_BEFORE
item_before_E2	SE_TEST_MEDICATIE_GROUPS_REPEAT.F_ADVE_6538_V11.IG_ADVE_UNGROUPED_4947.I_ADVE_ITEM_BEFORE
Adverse_event_E1_C1	SE_TEST_MEDICATIE_GROUPS_REPEAT.F_ADVE_6538_V11.IG_ADVE_ADVERSEEVENTS_7407.I_ADVE_ADVERSE_EVENT_678
Adverse_event_E1_C2	SE_TEST_MEDICATIE_GROUPS_REPEAT.F_ADVE_6538_V11.IG_ADVE_ADVERSEEVENTS_7407.I_ADVE_ADVERSE_EVENT_678
Adverse_event_E1_C3	SE_TEST_MEDICATIE_GROUPS_REPEAT.F_ADVE_6538_V11.IG_ADVE_ADVERSEEVENTS_7407.I_ADVE_ADVERSE_EVENT_678
Adverse_event_E2_C1	SE_TEST_MEDICATIE_GROUPS_REPEAT.F_ADVE_6538_V11.IG_ADVE_ADVERSEEVENTS_7407.I_ADVE_ADVERSE_EVENT_678
Adverse_event_E2_C2	SE_TEST_MEDICATIE_GROUPS_REPEAT.F_ADVE_6538_V11.IG_ADVE_ADVERSEEVENTS_7407.I_ADVE_ADVERSE_EVENT_678
Adverse_event_E2_C3	SE_TEST_MEDICATIE_GROUPS_REPEAT.F_ADVE_6538_V11.IG_ADVE_ADVERSEEVENTS_7407.I_ADVE_ADVERSE_EVENT_678
Date_onset_E1_G1	SE_TEST_MEDICATIE_GROUPS_REPEAT.F_ADVE_6538_V11.IG_ADVE_ADVERSEEVENTS_7407.I_ADVE_DATE_ONSET_7692

Study Data Column	OC Target Item	Study Subject ID?
subject_id	Use link button 'CopyTarget' to fill this cell with the selected target item	<input checked="" type="checkbox"/>
item_before_E1	SE_TEST_MEDICATIE_GROUPS_REPEAT.F_ADVE_6538_V11.IG_ADVE_UNGROUPED_4947.I_ADVE_ITEM_BEFORE	<input type="checkbox"/>
item_before_E2	SE_TEST_MEDICATIE_GROUPS_REPEAT.F_ADVE_6538_V11.IG_ADVE_UNGROUPED_4947.I_ADVE_ITEM_BEFORE	<input type="checkbox"/>
Adverse_event_E1_C1	SE_TEST_MEDICATIE_GROUPS_REPEAT.F_ADVE_6538_V11.IG_ADVE_ADVERSEEVENTS_7407.I_ADVE_ADVERSE_EVENT_678	<input type="checkbox"/>
Adverse_event_E1_C2	SE_TEST_MEDICATIE_GROUPS_REPEAT.F_ADVE_6538_V11.IG_ADVE_ADVERSEEVENTS_7407.I_ADVE_ADVERSE_EVENT_678	<input type="checkbox"/>
Adverse_event_E1_C3	SE_TEST_MEDICATIE_GROUPS_REPEAT.F_ADVE_6538_V11.IG_ADVE_ADVERSEEVENTS_7407.I_ADVE_ADVERSE_EVENT_678	<input type="checkbox"/>
Adverse_event_E2_C1	SE_TEST_MEDICATIE_GROUPS_REPEAT.F_ADVE_6538_V11.IG_ADVE_ADVERSEEVENTS_7407.I_ADVE_ADVERSE_EVENT_678	<input type="checkbox"/>
Adverse_event_E2_C2	SE_TEST_MEDICATIE_GROUPS_REPEAT.F_ADVE_6538_V11.IG_ADVE_ADVERSEEVENTS_7407.I_ADVE_ADVERSE_EVENT_678	<input type="checkbox"/>
Adverse_event_E2_C3	SE_TEST_MEDICATIE_GROUPS_REPEAT.F_ADVE_6538_V11.IG_ADVE_ADVERSEEVENTS_7407.I_ADVE_ADVERSE_EVENT_678	<input type="checkbox"/>
Date_onset_E1_G1	SE_TEST_MEDICATIE_GROUPS_REPEAT.F_ADVE_6538_V11.IG_ADVE_ADVERSEEVENTS_7407.I_ADVE_DATE_ONSET_7692	<input type="checkbox"/>

Study Data Column	OC Target Item	Study Subject ID?
Adverse_event_E1_C3	SE_TEST_MEDICATIE_GROUPS_REPEAT.F_ADVE_6538_V11.IG_ADVE_ADVERSEEVENTS_7407.I_ADVE_ADVERSE_EVENT_678	<input type="checkbox"/>
Adverse_event_E2_C1	SE_TEST_MEDICATIE_GROUPS_REPEAT.F_ADVE_6538_V11.IG_ADVE_ADVERSEEVENTS_7407.I_ADVE_ADVERSE_EVENT_678	<input type="checkbox"/>
Adverse_event_E2_C2	SE_TEST_MEDICATIE_GROUPS_REPEAT.F_ADVE_6538_V11.IG_ADVE_ADVERSEEVENTS_7407.I_ADVE_ADVERSE_EVENT_678	<input type="checkbox"/>
Adverse_event_E2_C3	SE_TEST_MEDICATIE_GROUPS_REPEAT.F_ADVE_6538_V11.IG_ADVE_ADVERSEEVENTS_7407.I_ADVE_ADVERSE_EVENT_678	<input type="checkbox"/>
Date_onset_E1_G1	SE_TEST_MEDICATIE_GROUPS_REPEAT.F_ADVE_6538_V11.IG_ADVE_ADVERSEEVENTS_7407.I_ADVE_DATE_ONSET_7692	<input type="checkbox"/>
Date_onset_E1_G2	SE_TEST_MEDICATIE_GROUPS_REPEAT.F_ADVE_6538_V11.IG_ADVE_ADVERSEEVENTS_7407.I_ADVE_DATE_ONSET_7692	<input type="checkbox"/>
Date_onset_E1_G3	SE_TEST_MEDICATIE_GROUPS_REPEAT.F_ADVE_6538_V11.IG_ADVE_ADVERSEEVENTS_7407.I_ADVE_DATE_ONSET_7692	<input type="checkbox"/>
date_onset_E2_C1	SE_TEST_MEDICATIE_GROUPS_REPEAT.F_ADVE_6538_V11.IG_ADVE_ADVERSEEVENTS_7407.I_ADVE_DATE_ONSET_7692	<input type="checkbox"/>
date_onset_E2_C2	SE_TEST_MEDICATIE_GROUPS_REPEAT.F_ADVE_6538_V11.IG_ADVE_ADVERSEEVENTS_7407.I_ADVE_DATE_ONSET_7692	<input type="checkbox"/>
date_onset_E2_C3	SE_TEST_MEDICATIE_GROUPS_REPEAT.F_ADVE_6538_V11.IG_ADVE_ADVERSEEVENTS_7407.I_ADVE_DATE_ONSET_7692	<input type="checkbox"/>



## Appendix: Error messages

- 1- User Manual not found: User manual can't be found in the installation directory. See section 3.1
- 2- Can't open selected data file "thedatafile.txt ", can't continue. Delimiter =                      Items per line = 20: The data file can't be opened, it may not exist or you don't have enough privileges to open it.
- 3- Failed to start Acrobat reader: acro32 doesn't exist to open the document file. Go to the installation directory and double click on the document file to open it manually.
- 4- Do you want to load your previous grid?: The program saves the last grid used; if you want to reload the last saved grid, click yes.
- 5- Can't generate grid dump file (see log file for details - Do you have enough permissions to write in target folder?): You probably have no write permissions; see section 3.12 to see where the log file is.
- 6- DataImport\_\* files will be overwritten. Do you want to delete the old files?: If you run the program on a directory which older DataImport files exist, they will be overwritten. Click No if you don't want to lose your old files, save them elsewhere and try again.
- 7- Please select (only) one field as STUDY SUBJECT ID by using check box; You have 2 selected.: Only one and only one study subject id may be selected.
- 8- "Please select at most one field as STUDY SUBJECT SEX/PERSON ID/SUBJECT DATE OF BIRTH/STUDY START DATE by using check box; You have 2 selected.: These can only be checked for one row maximum.
- 9- Please enter location: Location name is mandatory.
- 10- Input data file format incorrect at line = 26 Expecting: 12; found: 13 items; this is the faulty line: At this line there is a mismatch with number of columns and number of data items. (12 columns and 13 items)
- 11- Duplicate key "thekeyvalue" at line = 34: If the duplicate key check is performed (section 3.12) and a duplicate key is detected, this message will be displayed.
- 12- Subject sex can be only 'f' or 'm'. You have "MALE" at line 12. Index: 5. Exiting...The generated files ARE INCOMPLETE AND CAN NOT BE USED : At the 5<sup>th</sup> column there should be the gender code and this must be conform section 3.9.
- 13- Invalid subject birth date "'12061998'" at line 23. Index: 7. Exiting...The generated files ARE INCOMPLETE AND CAN NOT BE USED: At the 7<sup>th</sup> column there should be the birth date but that can't be converted to ODM format. See section 3.8
- 14- Invalid subject start date "'12061998'" at line 23. Index: 7. Exiting...The generated files ARE INCOMPLETE AND CAN NOT BE USED: At the 7<sup>th</sup> column there should be the start date but that can't be converted to ODM format. See section 3.8
- 15- Exception while reading data file: Unexpected error; see the log file for details.
- 16- Error while getting STUDYEVENT Repeating Key: Cant resolve the DataItemColumnName Adverse\_event\_3 + ". The proper name should look like 'DataItem\_E2\_C3 Where E2 means Event repeating key = 2 and C3 means Group repeating key = 3. Exiting...The generated files ARE INCOMPLETE AND CAN NOT BE USED: The name of the data item column for repeating events and groups has a format of DataItem\_Ex\_Cy where x=repeat key study event and y=repeating group. This is not the case with Adverse\_Event\_3. See section 3.17.
- 17- Error while getting GROUP Repeating Key: See 16.
- 18- Wrong index at: 67. Exiting...The generated files ARE INCOMPLETE AND CAN NOT BE USED"; The program is unable to get the location of the item at the specified line.
- 19- Wrong replace couple: Replace couple is niet conform section 3.10
- 20- Can't get study event/group/event/CRF/item definitions; please check the format of the file: The meta file created by OpenClinica is probably corrupt. Use an XML editor to see whats wrong; eventually regenerate the file.
- 21- Please enter or select correct input files: Either type two file names separated by a semicolon (;) or use browse button.: Specify the 2 input files correctly.
- 22- Can't open selected data file, PROBABLY file doesn't belong to you or is read only. Please make sure you are the owner, then try again: This happens mostly when the data file is saved on another computer or by someone else than the user who is running the program now. Make a copy of the data file and use that one as input.
- 23- Can't open selected OC meta file, can't continue: See log file.
- 24- Not all Items in the selected CRF could be matched. For the list of UNMATCHED Items, see the progress textbox below. You can match those items by using the comboboxes above. Control the matched items too, as the matching can not be 100% correct!: See section 3.6

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- 25- All Items in the selected CRF could be matched. Control the matched items as the matching can not be 100% correct!: See section 3.6
- 26- Process is not finished yet. Are you sure you want to stop this program?: This is issued when the cancel button is hit. The process has to be rerun after this.
- 27- Please use all of the comboboxes above to define a target item. (there are still -- select --'s up there): When the "copy target" link button is clicked, all of the target item comboboxes must be selected. See section 3.6
- 28- Please read input files first: Hit the "Read input files" button to do this.