

341. Import CDISC-ODM

What is ODM?

The CDISC Operational Data Model (ODM), maintained by the CDISC XML Technologies Team, is designed to facilitate the regulatory-compliant acquisition, archive and interchange of metadata and data for clinical research studies. ODM is a vendor neutral, platform-independent format for interchange and archive of clinical study data. The model includes clinical data along with its associated metadata, administrative data, reference data and audit information. All the information that needs to be shared among different software systems during the study setup, operation, analysis, submission or for long-term retention as part of an archive is included in the model. See details on the CDISC ODM certification program, including a list of ODM-certified company products.

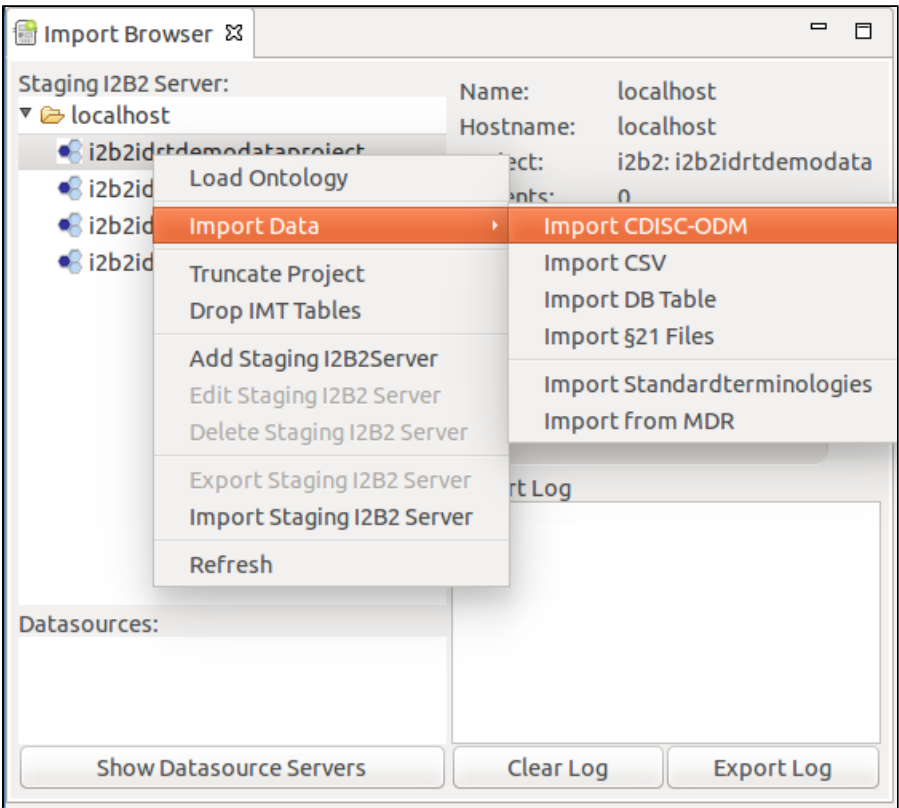
See [Official CDISC-ODM Page](#)

Example File

In the github repository, you can find some [CDISC-ODM Example Files](#).

Import CSDISC-ODM

To import your CDISC-ODM files to i2b2, you have to right click the i2b2 project in the [Import Browser](#) and select Import Data -> Import CDISC-ODM.



A new window opens, where you can set different options.

CDISC-ODM Import Settings

CDISC-ODM Import Settings

Truncate i2b2 Project?
☐

Truncate Previous Queries?
☐

Database Indexing
☐ Ignore
☐ Stop/Start
☒ Drop/Create

Set patient_count after import
☒

CDISC-ODM Folder

...

Include complete Codelists?
☒

Include PIDs?
☐

Save Settings?
☐

Cancel

Finish

Name	Description
Truncate i2b2 Project?	If you check this, the project will be truncated before the data is uploaded.
Truncate Previous Queries?	This will truncate the previous queries tables.
Database Indexing	Ignore: Don't touch the indexes; Stop/Start: Stop the indexes before the upload and start them afterwards; Drop/Create: Drop the indexes before the upload and create them from scratch afterwards.
Set patient_count after import	This will fill the c_totalnum column.
CDISC-ODM Folder	Here you can select the folder that contains all CDISC-ODM files you want to upload.
Include complete Codelists?	This will generate i2b2 ontology items that are in a codelist, even if there are no patients for it.
Include PIDs?	This will generate a new i2b2 folder containing the patient IDs (PID) as items.
Save Settings?	This will save the settings for the next import. Note: The truncate checks are never saved.

If you hit **finish** the upload starts. You can observe the progress in the progress bar of the [Import Browser](#).

After the import is finished, you can load the i2b2 ontology with the [Mapping Editor](#). If you loaded the sample data linked above, you should see the following result in the Mapping Editor View:

Mapping Editor

Staging i2b2: i2b2idrtmodataproject

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🔑

Ontology - [500]

- ▼ Patientendaten - [500]
 - ▼ INSEP - [500]
 - ▼ MetaDataVersion - [500]
 - ▼ 001 Day 1 - [500]
 - ▼ Basisdata - [500]
 - ▼ Ungrouped - [500]
 - ▼ 001 Age - [500]
 - 📄 001 Age (Numerical Query) - [500]
 - ▼ 002 Gender - [500]
 - 📄 Female - [250]
 - 📄 Male - [250]
 - ▶ 003 Admission - [500]
 - ▶ 004 Admission from other hospital? - [500]
 - ▶ 005 ITS-Admission - [500]
 - ▶ 006 SAPS II-Score - [500]
 - ▶ 009 Discharge - [500]
 - ▶ 010 Discharge ITS - [500]
 - ▶ 011 Status at ITS-Discharge - [500]
 - ▶ 012 Status at Hospital-Discharge - [500]
 - ▶ 013 Patient with severe Sepsis? - [500]

The CDISC-ODM Importer keeps the hierarchy the file suggests. You can make changes to that with the editing functionality of the [Mapping Editor](#).