OpenVigil 1 – Documentation for usage of Non-FDA pharmacovigilance data with OpenVigil 1

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1.   Introduction

OpenVigil 1 is capable of loading other pharmacovigilance data than just U.S. american FDA AERS files. OpenVigil 1 makes only a few assumptions about your data. Thus it is quite easy to adapt your dataset to the OV1-format.

2. Technical issues

However, some changes need to be done to the data files and importer. There will be some kind of primary key for each report. This will be your later individual safety report number (ISR).
The OpenVigil 1 importer expects the FDA LAERS format used between 2005Q3 and 2012Q2. OpenVigil 1 needs at least DRUG.DRUGNAME, DRUG.ISR, REAC.PT, REAC.ISR. It is helpful to include more data, e.g., DEMO.ISR=DEMO.CASENO, DEMO.AGE, DEMO.AGE_COD, DEMO.GNDR_COD, DEMO.FDA_DT.
In addition, any other tables (e.g., DMAP, see below) can be loaded and will be used automatically as long as they contain an ISR-column.

3. Data cleaning

Depending on the datasource, the DRUG.DRUGNAME might be a verbatim text string that needs to be mapped to a definite drugname (active substance). E.g., the U.S. american FDA AERS DRUG.DRUGNAME must be mapped while the Canadian and the German pharmacovigilance data use both brandnames and already mapped drugnames. However, you might consider removing the salt-component in the drugname.

As extension to the FDA data format, OpenVigil 1 features the DMAP-table which can contain mapping between brandname and drugname. Fig. 1 shows an example report how German drugs and brands were mapped.

Individual Safety Report #1465331

The following is an extract from the different tables in the database that contain information to this individual safety report (ISR). E.g., the table DRUG contains information of all drugs given to the subject; the table REAC lists all observed adverse events. A description of the contents of the other tables and the meanings of the fields can be found in the chapter B (data element describtion) of this FDA document.

Showing all records in every data table concerning case #1465331...

Matching records in table "DEMO"

ISR	CASENO	I_F_COD	FOLL_SEQ	IMAGE	EVENT_DT	MFR_DT	FDA_DT	REPT_COD	MFR_NUM	MFR_SNDR	AGE	AGE_COD	GNDR_COD	E_SUB	WT	WT_COD	REPT_DT	OCCF
1465331	1465331	0			0000-00-00	0000-00-00	2007-11-26				25	YR	F		0		0000-00-00	

1 records found in this table.

Matching records in table "DMAP"

ISR	DRUG	BRAND	EXTRA	DOSE	ROUTE	DSRC
1465331	ethanol	alkohol				DMAPGERM
1465331	metamizol natrium	metamizol				DMAPGERM
1465331	paracetamol	paracetamol				DMAPGERM
1465331	ciprofloxacin	ciprofloxacin				DMAPGERM
1465331	diclofenac	diclofenac				DMAPGERM
1465331	magnesium oxid schwer	magno sanol				DMAPGERM
1465331	trospium chlorid	trospium chlorid				DMAPGERM
1465331	naratriptan hydrochlorid	naratriptan				DMAPGERM

8 records found in this table.

Matching records in table "DRUG"

ISR	DRUG_SEQ	ROLE_COD	DRUGNAME	VAL_VBM	ROUTE	DOSE_VBM	DECHAL	RECHAL	LOT_NUM	EXP_DT	NDA_NUM	DSRC
1465331	1465331001		ethanol	0						0000-00-00		DRUGGERM
1465331	1465331002		metamizol natrium	0						0000-00-00		DRUGGERM
1465331	1465331003		paracetamol	0						0000-00-00		DRUGGERM
1465331	1465331004		ciprofloxacin	0						0000-00-00		DRUGGERM
1465331	1465331005		diclofenac	0						0000-00-00		DRUGGERM
1465331	1465331006		magnesium oxid schwer	0						0000-00-00		DRUGGERM
1465331	1465331007		trospium chlorid	0						0000-00-00		DRUGGERM
1465331	1465331008		naratriptan hydrochlorid	0						0000-00-00		DRUGGERM

8 records found in this table.

Matching records in table "DSRC"

FNAME DT NERR_PARSER NERR_SQL TERR_PARSER TERR_SQL
There were no matching records in this table.

Matching records in table "INDI"

ISR DRUG_SEQ INDI_PT DSRC
There were no matching records in this table.

Matching records in table "OUTC"

ISR OUTC_CODE DSRC
There were no matching records in this table.

Matching records in table "REAC"

ISR	PT	DSRC
1465331	Suizidversuch	REACGERM
1465331	absichtliche Ueberdosis	REACGERM

2 records found in this table.

Fig 2: A single report with DMAP-table

Note that OpenVigil 1 has no drugname-mapping logic itself so it is not suitable to analyse uncleaned U.S. data!

4. OpenVigil 1 with German pharmacovigilance data

A preview of OpenVigil 1 with German pharmacovigilance data can be found here:

http://www.uni-kiel.de/pharmacology/pvt/openvigil-current-bfarm.php

Note that you need to use German naming conventions: Drugnames are expressed as INN (without the „-e" suffix in some cases), for adverse events the German MedDRA preferred terms are used (see fig. 2).

OpenVigil v1.2.7-GERMAN-nightly-20150828

This is a preview version of OpenVigil. Maybe, some calculations and buttons will not work as expected!

This version operates on *German pharmacovigilance* **data - please use GERMAN terms for adverse events and germanized INN-drugnames! Note that the user interface is not yet updated. Please ignore the FDA-specific terminology.**
Also note that the dataset is currently for proof-of-concept and thus not complete.

This web application permits you to process a query on pharmacovigilance data. Click **here for a tutorial** on how to use it. Further information/specifications can be found in the documentation. Limitations can be found in the OpenVigil Cave-At document.
Press show database info to display more information about the database structure and content. Refer to this overview of this installation to obtain detailed information, e.g., for citation of data extracted by this installation.
This installation uses data from 1995-01-05 to 2015-06-24 (according to reports dates (DEMO.FDA_DT)).

Step 1: Chose how to construct your query. Create query...

- ● using a Wizard in basic mode or
- ○ using a Wizard in professional mode or
- ○ in self-made structured query language (SQL) or
- ○ perform a disproportionality analysis (this analysis might take some minutes) or
- ○ show all records belonging to a specific ISR number (output only human-readable, no CSV!)

Step 2: Fill in at least one of the fields below to filter out the cases you are interested in. As result, you will get either a list of case numbers (ISR number) which you can click to get further information about every reported case or statistics on the frequency. Note that this search more is not very powerful; consider watching the tutorial and using the Wizard in professional mode or writing SQL queries yourself! Also note that you have to use the generic drug name and that both indication and adverse event are named according to the MedDRA terminology. OpenVigil will attempt to find the best match for the drugname and/or the adverse event that you have entered.

Drugname	paracetamol	Matching: exactly this drugname	Use original verbatim drugname (DRUG.DRUGNAME)
Adverse event		Matching: exactly this event	Use MedDRA terminology (REAC.PT)

Show results as ...

Agranulozytose
Suizidversuch
Leukopenie
Stevens-Johnson-Syndrom
Fieber
Epidermolysis acuta toxica
Pruritus
Uebelkeit
Ausschlag
Erbrechen

*) i.e., if either dr... adverse event are ...

Export results a... Please note that ...
Basic mode: Coun...

Fig. 1: A preview version of OpenVigil 1.2.7 working with a German dataset with an example list of autocomplete-terms as adverse reaction