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.
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:


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).
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