OpenVigiIFDA - Tutorial

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1. Introduction

OpenVigilFDA is a web-based user interface to the FDA Adverse Event Reporting System (AERS) database for extraction and analysis of drug/adverse event safety reports using the **openFDA** online-API. This data is helpful for generating hypotheses for new adverse drug reactions, drug-drug-interactions and safety comparisons. openFDA aims at providing a clean and curated access to the underlying AERS database and can count reports stratified to an extraction condition. Results are used for statistics and reported to the user via HTML or several other outputs.

2. Technical issues

openFDA has some technical limitations, e.g., lists are truncated after 100 items, or extracting more than 5000 reports per query is not possible. This affects mostly disproportionality analyses (DPA) and any attempts to group and count results (limit 100 results). Some results will thus be incomplete. OpenVigil 2 is thus recommended for analyses of small numbers.

3. Data cleaning

openFDA takes care of the data cleaning. The data cleaning is currently reported to be 86% and is probably lower because of some mismappings and duplicates (Shin 2014). Before 2015-08-17, the fraction of reports with openFDA-enabled drugname mapping was 87%.

On 2015-08-17, the FDA updated the database and the drugname-mapping. The mapped fraction is now "just" 81%. However, it appears that several mismappings were corrected: E.g., before 2015-08-17, the product "IBUPROFEN" was incorrectly mapped to the active substances "DIPHENHYDRAMINE CITRATE + IBUPROFEN".

4. Screenshots

OpenVigilFDA offers data extraction, counting and analysis interfaces similar to those of OpenVigil 1 or 2. Furthermore, clinical and scientific scenarious are available:

Open Vigil FDA v1.0rc3
OpenVigilFDA is a web-based user interface to the FDA Adverse Event Reporting System (AERS) database for extraction and analysis of drug/adverse event safety reports using the openFDA online-API. This data is helpful for generating hypotheses for new adverse drug reactions, drug-drug-interactions and safety comparisons , openFDA aims at providing a clean and curated access to the underlying AERS database and can count reports stratified to an extraction condition. Results are used for statistics and reported to the user via HTML or several other outputs.
Overview of software version and database update time More Info on Pharmacovigilance Show/Hide More about OpenVigilFDA: Show/Hide Cave-at/Limitations/Disclaimers: Show/Hide
Step 1: Which data do you have, e.g., drugname, adverse event, age, indication)? Which data do you want to extract or analyze (e.g., by counting or by a disproportionality analysis (DPA))? Chose a way of extraction, counting or analysis for one or more subpopulations/conditions or use the clinical or scientific special analysis scenarios:
Basic data extraction or counting
 Use drug, event and/or indication as search filters to browse or count reports Example: How many reports are there for 'metformin'? Which adverse events were filed for 'metformin'?
 Create a more complex query using boolean logic, parentheses and a list of openFDA datafields. Example: Use this for complex filtering or stratification conditions.
• Disproportionality analyses (DPA): Significant associations between condition #1 (e.g., drug) and condition #2 (e.g., an event)
 Is there a connection between a drug and an adverse event? Example: Is there any statistical evidence for an association based on the disproportionality of reporting of one drug and one adverse event, i.e., is the event putative adverse drug reaction? (Simple 1 drug x 1 event DPA and browse results)
Example: Which drugs should be discontinued first after a new adverse event has occured? (Complex DPA searching for one event in a list of drugs; processing might take some minutes) • Compare two drugs concerning their safety profile and search for possible drug-drug-interaction. Example: How do 'gabapentin' and 'pregabalin' differ in their safety profile? Which events are overproportionally reported for the combination of two drugs (Complex DPA filtering multi-item for two drugs, alone/combined; processing might take some minutes) • Direct database access • Custom build openAPI request: If you know the openFDA API datafields and query syntax, you can enter the request textstring yourself. Examples shown below; use this for very complicated queries. • Show single safety report: Show all records belonging to a specific safety report id to inspect every item manually. Example: For random inspection and validation of previously extracted reports.
Step 1b: Optional: Refine drugname-mapping and restrict the report background to a subpopulation, e.g., males 40-60 years, treated for HYPERTENSION). Show/Hide
Step 2: Use the fields below to filter out the cases you are interested in. Using no filter criteria results in all reports (whole dataset) being selected.
Drugname
Adverse event
Drugclass (Mechanism of Action)
Indication
Count the number of results using a factor (optional) T
Export results as human readable HTML or Solventresults as human readable HTML or Solventresults as CSV output (counting result lists).
Open new tab/window and process query >>

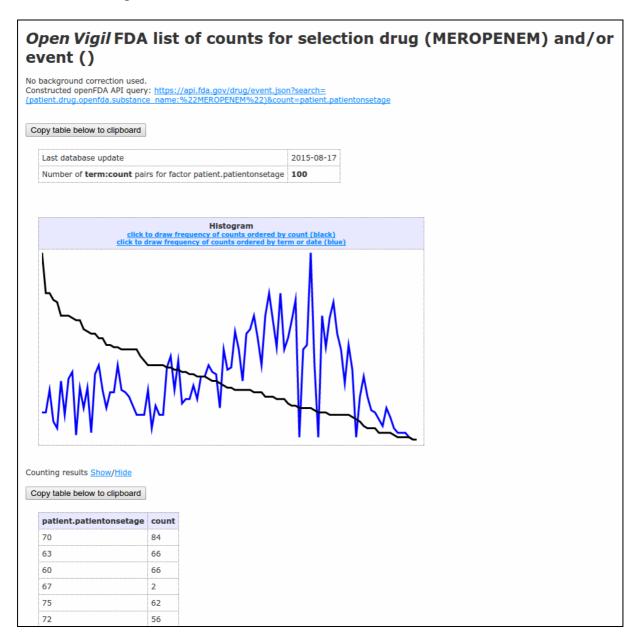
You can define a certain population background to focus on a certain subpopulation or to exclude confounding factors:

Step 1b : Optional: Refine drugname-mapping and restrict the report background to a subpopu	lation, e.g., males 40-60 ye	ears, treated for HYPERTENSION). Show/Hide
Drugname-Mapping (experimental!): Select openFDA-API datafield to use for any drugnames: [openFDA substance_name	▼
Background-correction/restriction: Do you want to focus on special subpopulations selected	d by gender, age, indication	etc.? Select the available filters here:
Background correction		
Only include openFDA-cleaned data? Only consider reports with successful drugname-mapping (openFDA-data). Recommended.	0	
Minimum/maximum age (in years)		
Patient sex	unknown ▼	The state of the s
Minimum duration of treatment (in years)		
Drugname		
Drugclass (Mechanism of Action)		
Adverse event		
Indication		
Verbatim openFDA query string		
		.:
Other configuration options:		
Whenever possible, count the top drug, events, etc. reported for this selection:		

Your subpopulation of interest is further analysed and the drugs, events and indications being frequently found in these reports are shown. They might indicate any confounders. E.g., the antiemetic ondansetron appears to be associated with severe disorders of the blood. Looking at the top co-prescribed drugs, it is easy to see that this finding is confounded by the frequent use of (emetic!) chemotherapeutics like cisplatin together with ondansetron.

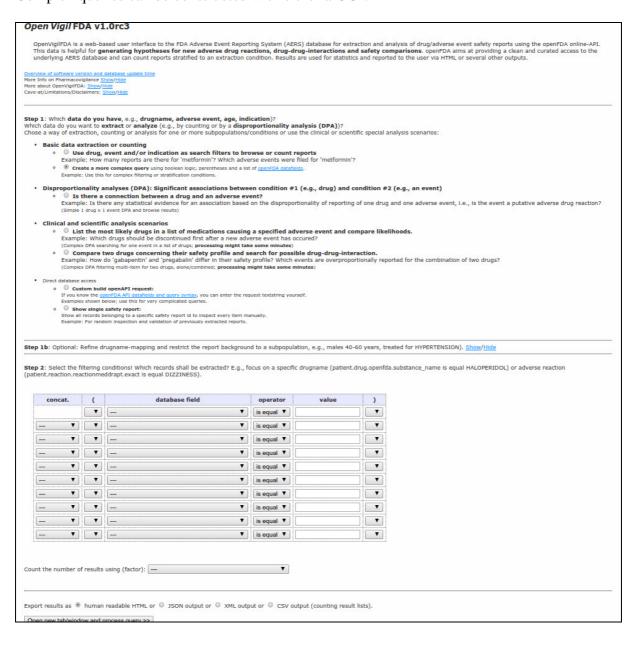
pen Vigil FDA safety report bro	wser for selection drug (MEROPENEM) and/or	ever
ackground correction used. tructed openFDA APT query: https://api.fda.gov/drug/eyent.json?s	search=(patient.drug.openfda.substance_name;%22MEROPENEM%22)	
py table below to clipboard		
Last database update	2015-08-17	
Number of matching records for this selection/group	3979	
Possible Confounders: Which drugs, events, indications, agus them to refine the subpopulations you want to compare (e.g., unma	ges or sex are most frequent among the subpopulation selected above? sking signals by using (NOT this drug)) or include them into the background correction	
Gender distribution	2122 (53.33%) male 1612 (40.51%) female 100 (2.51%) unknown	
Age distribution Age (Number of reports)	70 (84) 63 (66) 60 (66) 67 (2) More results <u>Show/Hide</u>	
Top drugs Generic Name (Number of reports)	MEROPENEM (3979) VANCOMYCIN HYDROCHLORIDE (1116) FUROSENIDE (611) FLUCONAZOLE (584) More results Show/Hide	
Top medicinalproducts Productname (Number of reports)	MEROPENEM (3979) VANCOMYCIN (984) FLUCONAZOLE (500) FUROSEMIDE (425) More results Show/Hide	
Top drugclasses MoA Mechanism of Action (Number of reports)	Corticosteroid Hormone Receptor Agonists [MoA] (1025) Cytochrome P450 3A4 Inhibitors [MoA] (1010) Cytochrome P450 2C19 Inhibitors [MoA] (653) Cytochrome P450 2C9 Inhibitors [MoA] (614) More results Show/Hide	
Top adverse events Event (Number of reports)	PYREXIA (272) SEPSIS (199) PNEUMONIA (185) RESPIRATORY FAILURE (163) More results Show/Hide	
Top Indications Indication (Number of reports)	PRODUCT USED FOR UNKNOWN INDICATION (546) PROPHYLAXIS (361) PNEUMONIA (267) SEPSIS (222) More results Show/Hide	

Selections can be counted. Below is an example of the age distribution of all patients having issues with meropenem:



openFDA reports back the top-100-items for each count. The black line is an histogram of the original openFDA data, the blue line is an histogram with sorted keys (i.e., age sorted numeric).

Complex queries can be constructed with either a GUI:



... or by hand if you know the openFDA-syntax:

The contract of the contract o	Open Vigil FDA v1.0rc3
The contract of the contract o	reactions, drug-drug-interactions and safety comparisons. openFDA aims at providing a clean and curated access to the underlying AERS database and can count reports stratified to an extraction condition. Results are used for statistics and reported to the user via H
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Step 1b: Optional: Refine drugname-mapping and restrict the report background to a subpopulation, e.g., males 40-60 years, treated for HYPERTENSION). Ehree/Hidds Step 2: Enter a freely-constructed search query for the openFDA APII Possible search parameters are search-datafield:datavalue,_exist_idatafield; count-datafield; skip/limit=number of reports ties boolean logic (ANO, OR) to concatenate. Query: You can store your query in the textarea below. It will be saved in your browser's cookies for later usage. search-patient, drug, openfda, generic name. exact: (%2005)ERNONE-AND-ERHINVI-ESTRADIO. (%22) +AND-patient, reaction, reactionmeddrapt, exact: (%220EAIN/22) +AND-receivedate: ([1989-86-29-10+2815-88-11]) &count-receivedate6skip=0 search-patient, drug, openfda, generic name: (alloquirinol) +AND-patient, reaction, reactionmeddrapt. ENTER YOUR OWNEY HERE IT WILL BE SAYED IN YOUR BROWSER COOKIES SO YOU CAN RE-USE AND POSSIBLY MODIFY IT OVER AND OVER.	
Step 2: Enter a freely-constructed search query for the openFDA APII Possible search parameters are search-datafield:datavalue_exist_datafield; count-datafield; skip/limit=number of reports Query: You can store your query in the textarea below. It will be saved in your browser's cookies for later usage. Search-patient.drug.openfda.generic_name.exact:(%22PAIN*22)+&ND*receivedate:([1989-06-29+IQ+2015-88-11])&count-receivedate&kip=0 search-patient.drug.openfda.generic_name.exact:(%22PAIN*22)+&	Example: For random inspection and validation of previously extracted reports.
Possible search parameters are search—datafield:datavalue_exist_idatafield; count—datafield; skip/limit=number of reports the boolean logic (AND, ON) to conciterate. Query: You can store your query in the textares below. It will be saved in your browser's cookies for later usage. Search—patient, drug_openida_generic_name_exact: (%22080SPIRENDME_+AND-EXTRADIOL%22)+AND-patient_reaction_reactionmeddrapt_exact: (%22081%22)+AND-receivedate: ([1989-86-29+TQ+2015-88-11]) &count=receivedate&akin=8 search—patient_drug_openida_generic_name: (alloquirinol)+AND-patient_reaction_reactionmeddrapt_exact: (%22080SPIRENDME_+AND-EXCEIVEDATE: ([1989-86-29+TQ+2015-88-11]) &count=receivedate&akin=8 search—patient_drug_openida_generic_name: (alloquirinol)+AND-patient_reaction_reactionmeddrapt_exact: (\$1989-86-29+TQ+2015-88-11]) &count=receivedate&akin=8 search—patient_drug_openida_generic_name: (alloquirinol)+AND-patient_receivedate&akin=8 search—patient_drug_openida_generic_name: (alloquirinol	Step 1b: Optional: Refine drugname-mapping and restrict the report background to a subpopulation, e.g., males 40-60 years, treated for HYPERTENSION). Shoulfittle
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Use boolen logic (AND, ON) to concatenate. Query: Query: Query: Query: Search—patient.drug.openfda.generic_name.exact: (%22005F1EENOME-AND-ETHING-ESTRADIOL%22)+AND-patient.reaction.reactionmeddrapt.exact: (%220EIN%22)+AND-receivedate: ([1989-06-29+IQ-2015-08-11])&count=receivedate&kip=0 search—patient.drug.openfda.generic_name: (allopurinol)+AND-patient.reaction.reactionmeddrapt: (rash)+AND-receivedate* ([19606630+IQ-20150011])&limit=16&kip=0 HIT RIUS ONN QUERY HEBE ENTER YOUR ONN QUERY HEBE Export results as ® human readable HTML or © JSON output or © XML output or © CSV output (counting result lists).	Step 2: Enter a freely-constructed search query for the openFDA APII
You can store your query in the textarea below. It will be saved in your browser's cookies for later usage. search-patient.drug.openfda.generic_name.exact: (%220805PIRENOME+AND-ETHINYL-ESTRADIOL%22)+AND-patient.reaction.reactionmeddrapt.exact: (%2204IN%22)+AND-receivedate: ([1989-06-29+[0+2015-08-11])&count-receivedate&kip=0 search-patient.drug.openfda.generic_name: (allopurinol)+AND-patient.reaction.reactionmeddrapt: (rash)+AND-receivedate: ([19060630+TQ-20150011])&limit=16skip=0 HENTE YOUR ON QUERY HERE IT WILL 8E SAYED IN YOUR BROWSER COOKIES SO YOU CAN RE-USE AND POSSIBLY MODIFY IT OVER AND OVER.	Possible search parameters are search-datafield/datavalue_exist_'idatafield'; count-datafield'; skip/limit=number of reports Use booken logic (AND, OR) to concaterante.
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search=matient.drug.openfda.generic_name:(allopurinol)+AND-patient.reaction.reactionmeddramt:(rash)+AND-receivedate:([19060630+TQ+20150811])&limit=16sktp=0 ENTER YOUR OWN QUERY HERE IT WILL BE SAVED IN YOUR BROWSER COOKIES SO YOU CAN RE-USE AND POSSIBLY MODIFY IT OVER AND OVER. Export results as ® human readable HTML or © 150N output or © XML output or © CSV output (counting result lats).	You can store your query in the textarea below, it will be saved in your browser's cookies for later usage.
search=matient.drug.openfda.generic_name:(allopurinol)+AND-patient.reaction.reactionmeddramt:(rash)+AND-receivedate:([19060630+TQ+20150811])&limit=16sktp=0 ENTER YOUR OWN QUERY HERE IT WILL BE SAVED IN YOUR BROWSER COOKIES SO YOU CAN RE-USE AND POSSIBLY MODIFY IT OVER AND OVER. Export results as ® human readable HTML or © 150N output or © XML output or © CSV output (counting result lats).	search-patient.drug.openfdg.generic_name.exact:(%220B0SPIRENONE-AND-ETHINYL-ESTRADIOL%22)+AND+patient.reaction.reactionmeddrapt.exact:(%220AIN-22)+AND+receivedate:(f)1989-66-29+T0+2015-88-111)&count=receivedate
EXPORT results as ® human readable HTML or © 350N output or © XML output or © CSV output (counting result lats).	
IT WILL BE SAYED IN YOUR BROWSER COOKIES SO YOU CAN RE-USE AND POSSIBLY MODIFY IT OVER AND OVER. Export results as ® human readable HTML or © JSON output or © XML output or © CSV output (counting result lats).	
Export results as ® human readable HTML or © 150N output or © XML output or © CSV output (counting result lists).	LENTER YOUR OWN QUERY HERE. TIT WILL BE SAUPE IN YOUR BROWSER COOKIES SO YOU CAN RELISE AND DISSTRIY MODIFY IT OVER AND OVER
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Onen new tablisindra and noncess many >>	Export results as 😻 human readable HTML or 💿 JSON output or 💿 XML output or 💿 CSV output (counting result lists).
	Open new tab/window and process query >>

This is an example report of an analysis of disproportionality for the simple 2x2 design: Is the use of the drug "sirolimus" connected to the adverse event "urticaria"?

Open Vigil FDA analysis of disproportionality

No background correction used. Extracting data (this can take up to 10 seconds)...<u>Show/Hide</u>

Copy table below to clipboard

Groups	This drug (SIROLIMUS)	Other drugs	Sums
This event (URTICARIA)	9	28349	28358
	DE	dE	E
Other event	5667	4976111	4959096
	De	de	e
Sums	5676	4981778	4987454
	D	d	N (total)

Copy table below to clipboard

Disproportionality indicators	Value	Interpretation		
%DrugEvent/Drug	0.15856	Percentage of this drug-this adverse event vs this drug-all adverse events		
Chi squared Yates (chisq)	16.12163	Does the 2x2 table have a normal distribution (chi squared dist.)? Values greater than 4 correspond to p<0.05.		
Relative Reporting Ratio (RRR)	0.27887			
Proportional Reporting Ratio (PRR)	0.27864	These ratios compare the observed counts to expected counts and allow to quantify the additional risk/odds the drug and event selected above compared to the general background noise.		
Reporting Odds Ratio (ROR)	0.27877	Rougly, RRR/PRR/ROR values greater than 2 indicate that this drug-adverse event-combination is 2-fold more likely than all other combinations.		
Information Component (IC)	-1.84233	3		

Interpretation: According to the criteria by Evans 2001, which requires a report count > 3 (this combination: 9) and a PRR > 2 (here: 0.3) and a Chisquared > 4 (here: 16.1) this drug and event are probably **unrelated**.

Query execution time is 2.72 seconds.

You can also view individuel safety reports:

Open Vigil FDA safety report browser for selected reports No background correction used. Constructed openFDA API query: https://api.fda.gov/drug/event.json?search=safetyreportid:10003494 Copy table below to clipboard Last database update 2015-08-17 Number of matching records for this selection/group <u>Possible Confounders</u>: Which drugs, events, indications, ages or sex are most frequent among the subpopulation selected above? Use them to refine the subpopulations you want to compare (e.g., unmasking signals by using (NOT this drug)) or include them into the background correction. Gender distribution 1 (100%) female Age distribution 49 (1) Age (Number of reports) MEROPENEM (1) GENTAMICIN SULFATE (1) CLARITHROMYCIN (1) CEFUROXIME SODIUM (1) More results Show/Hide Top drugs Generic Name (Number of reports) ZITHROMAX (1) VIBRAMYCIN (1) Top medicinalproducts TIMENTIN (1) PRIMAQUINE (1) More results Show/Hide Productname (Number of reports) P-Glycoprotein Inhibitors [MoA] (1) Cytochrome P450 3A4 Inhibitors [MoA] (1) Cytochrome P450 3A Inhibitors [MoA] (1) Top drugclasses MoA Mechanism of Action (Number of reports) Top adverse events Event (Number of reports) Drug hypersensitivity (1) Top indications Indication (Number of reports) Copy table below to clipboard Safety report #10003494 Browse reports - #0/1 Next >> Receivedate 20140312 Reporter/Company US-PFIZER INC-2014070054 Patient age 49 years Patient sex female This report lists 11 drugs. Copy table below to clipboard Medicinalproduct Substance name(s) Dosage **Drug class** Form ZITHROMAX AZITHROMYCIN DIHYDRATE 500 MG, UNK CAPSULE, HARD 100 MG, UNK VIBRAMYCIN CEFUROXIME SODIUM + CEFUROXIME UNK GENTAMICIN SULFATE GENTAMICIN SULFATE +

UNK

To provide detailed information about the software and dataset used for an analysis, you should include the overview page in your publication:

py table below to clipboard	
component	status, e.g., version, release date, count
OpenVigiIFDA version string:	Open VigiI FDA v1.0rc3
OpenVigiIFDA license/contact/website:	GNU Public License (GPL) version 2 Project developer: ruwen.boehm@pharmakologie.uni-kiel.de Website: openvigil.sf.net
PHP version:	5.2.17
openFDA meta.disclaimer:	openFDA is a beta research project and not for clinical use. While we make every effort to ensure that data is accurate, you should assume all results are unvalidated.
openFDA meta.license:	http://open.fda.gov/license
openFDA meta.last_updated:	2015-08-17
openFDA meta.results.total for whole dataset:	4987454
openFDA meta.results.total with patient.drugs.openfda:	4084399
Percentage of openFDA-tagged safety reports:	81.89