**DRUG EVENT**

https://api.fda.gov/drug/event

API status and freshness API OK | Updated 2015-01-21 | Data current through 2014-06-30

The openFDA drug adverse event API returns data from the [FDA Adverse Event Reporting System (FAERS)](https://open.fda.gov/data/faers/), a database that contains information on adverse event and medication error reports submitted to FDA. Currently, this data covers publically releasable records submitted to the FDA from 2004-2013. The data is updated quarterly.

An adverse event is submitted to the FDA to report any undesirable experience associated with the use of a medical product in a patient. For drugs, this includes serious drug side effects, product use errors, product quality problems, and therapeutic failures for prescription or over-the-counter medicines and medicines administered to hospital patients or at outpatient infusion centers.

Reporting of adverse events by healthcare professionals and consumers is voluntary in the United States. FDA receives some adverse event reports directly from healthcare professionals (such as physicians, pharmacists, nurses and others) and consumers (such as patients, family members, lawyers and others). Healthcare professionals and consumers may also report adverse events to the products’ manufacturers. If a manufacturer receives an adverse event report, it is normally required to send the report to FDA.

Disclaimer

FAERS data does have limitations. There is no certainty that the reported event (adverse event or medication error) was actually due to the product. FDA does not require that a causal relationship between a product and event be proven, and reports do not always contain enough detail to properly evaluate an event.  
  
Further, FDA does not receive reports for every adverse event or medication error that occurs with a product. Many factors can influence whether or not an event will be reported, such as the time a product has been marketed and publicity about an event.  
  
Submission of a safety report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event. The information in these reports has not been scientifically or otherwise verified as to a cause and effect relationship and cannot be used to estimate the incidence of these events.

In 2012, FDA changed from the Adverse Event Reporting System (AERS) to the FDA Adverse Event Reporting System (FAERS). There was a minor shift in terms as part of this transition. If you are using data from before December 2012, you should be aware of this shift.

**Responsible use of the data**

Adverse event reports submitted to FDA do not undergo extensive validation or verification. Therefore, **a causal relationship cannot be established between product and reactions listed in a report.** While a suspected relationship *may* exist, it is not medically validated and should not be the sole source of information for clinical decision making or other assumptions about the safety or efficacy of a product.

Additionally, it is important to remember that adverse event reports represent a small percentage of total usage numbers of a product. Common products may have a higher number of adverse events due to the higher total number of people using the product. In recent years the FDA has undertaken efforts to increase collection of adverse events. Increases in the total number of adverse events is likely caused by improved reporting.

**How adverse events are organized**

Adverse events are collected through a series of *safety reports.* Each is identified by a 8-digit string (for instance, 6176304-1). The first 7 digits (before the hyphen) identify the individual report, and the last digit (after the hyphen) is a checksum. Rather than updating individual records in FAERS, subsequent updates are submitted in seperate reports.

**Format**

Adverse event reports use the [ICH E2b/M2 version 2.1 standard.](http://estri.ich.org/e2br22/ICH_ICSR_Specification_V2-3.pdf) OpenFDA annotates the original records with [special fields.](https://open.fda.gov/drug/event/reference/#openfda-fields)

**Data downloads**

FDA releases [quarterly updates to FAERS data.](http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm082193.htm) OpenFDA uses these extracts, but processes the data further before supplying them through the API. During our beta period, we are investigating the best ways to offer direct downloads of data provided by the API.

There are no plans for the openFDA initiative to change the FAERS release protocols. At this time it is anticipated that FAERS downloads will continue to be available from the same site on the same quarterly schedule. OpenFDA is a research project to make access to these datasets easier, not replace the current process. The information available through openFDA is not for clinical production use and is in beta testing. While FDA makes every effort to ensure the data is accurate, it should be assumed that all results are not validated.

**Anatomy of a response**

This is a simulated openFDA API return for a non-count query. It is divided into two high-level sections, meta and results.

{

"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.",

"license": "http://open.fda.gov/license",

"last\_updated": "2014-08-01",

"results": {

"skip": 0,

"limit": 1,

"total": 1355

}

},

"results": [

{

...

}

]

}

**Meta**

For non-count queries, the meta section includes a disclaimer, a link to the openFDA data license, and information about the results that follow.

"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.",

"license": "http://open.fda.gov/license",

"last\_updated": "2014-08-01",

"results": {

"skip": 0,

"limit": 1,

"total": 1355

}

meta.disclaimer

**string**

Important details about the openFDA beta and limitations of the dataset.

meta.license

**string**

Link to a web page with license terms that govern data within openFDA.

meta.last\_updated

**string**

The last date when openFDA was updated. Note that this does not correspond to the last report date in the system. Rather, it is the last time openFDA received a system or data update.

meta.results.skip

**integer**

Offset (page) of results, defined by the skip [query parameter](https://open.fda.gov/api/reference/#query-parameters).

meta.results.limit

**integer**

Number of records in this return, defined by the limit [query parameter](https://open.fda.gov/api/reference/#query-parameters). If there is no limit parameter, the API returns one result.

meta.results.total

**integer**

Total number of records matching the search criteria.

**Results**

For non-count queries, the results section includes matching adverse event reports returned by the API.

Each adverse event report consists of these major sections:

* **Header:** General information about the adverse event
* **Patient Information:** Details on the patient who experienced the event, such as age, weight, sex, etc.
* **Drugs:** Information on the drugs taken while the event was experienced
* **Reactions:** Information on the reactions experienced by the patient

**Field-by-field reference**

**Header**

General information about the adverse event.

"safetyreport": "1234567-8",

"safetyreportversion": "17",

"receivedate": "20041025",

"receivedateformat": "102",

"receiptdate": "20040224",

"receiptdateformat": "102",

"serious": "1",

"seriousnesscongenitalanomali": "1",

"seriousnessdeath": "1",

"seriousnessdisabling": "1"

"seriousnesshospitalization": "1",

"seriousnesslifethreatening": "1",

"seriousnessother": "1",

"transmissiondate": "1",

"transmissiondateformat": "1",

"duplicate": "1",

"companynumb": "200501050",

"occurcountry": "US",

"primarysourcecountry": "US"

"primarysource": {

"qualification": "1",

"reportercountry": "UNITED STATES"

},

"reportduplicate": {

"duplicatesource": "NOVARTIS",

"duplicatenumb": "PHEH2006US00792"

},

"sender": {

"sendertype": "2",

"senderorganization": "FDA-Public Use"

},

"receiver": {

"receivertype": "6",

"receiverorganization": "FDA"

}

safetyreportid

**string**

The 8-digit Safety Report ID number, also known as the case report number or case ID. The first 7 digits (before the hyphen) identify an individual report and the last digit (after the hyphen) is a checksum. This field can be used to identify or find a specific adverse event report.

safetyreportversion

**string**

The version number of the safetyreportid. Multiple versions of the same report may exist, it is generally best to only count the latest report and disregard others. OpenFDA will only return the latest version of a report.

receivedate

**string**

Date that the report was *first* received by FDA. If this report has multiple versions, this will be the date the first version was received by FDA.

receivedateformat

**string**

Identifies the encoding format of the receivedate field. Always set to 102 (YYYYMMDD).

receiptdate

**string**

Date that *most recent information* in the report was received by FDA.

receiptdateformat

**string**

Identifies the encoding format of the receiptdate field. Always set to 102 (YYYYMMDD).

serious

**string**

1 = The adverse event resulted in death, a life threatening condition, hospitalization, disability, congenital anomali, or other serious condition.

2 = The adverse event did not result in any of the above.

seriousnesscongenitalanomali

**string**

This value is 1 if the adverse event resulted in a congenital anomali, and absent otherwise.

seriousnessdeath

**string**

This value is 1 if the adverse event resulted in death, and absent otherwise.

seriousnessdisabling

**string**

This value is 1 if the adverse event resulted in disability, and absent otherwise.

seriousnesshospitalization

**string**

This value is 1 if the adverse event resulted in a hospitalization, and absent otherwise.

seriousnesslifethreatening

**string**

This value is 1 if the adverse event resulted in a life threatening condition, and absent otherwise.

seriousnessother

**string**

This value is 1 if the adverse event resulted in some other serious condition, and absent otherwise.

transmissiondate

**string**

Date that the record was created. This may be earlier than the date the record was received by the FDA.

transmissiondateformat

**string**

Identifies the encoding format of the transmissiondate field. Always set to 102 (YYYYMMDD).

duplicate

**string**

This value is 1 if the report has had previous versions submitted. OpenFDA only shows the most recent version.

companynumb

**string**

Identifier for the company providing the report. This is self-assigned.

occurcountry

**string**

The name of the country where the event occurred.

primarysourcecountry

**string**

The country of the reporter of the event.

primarysource

**list**

Information about the source provider of the adverse event.

primarysource.qualification

**string**

An encoded value for the category of individual submitting the report.

1 = Physician

2 = Pharmacist

3 = Other Health Professional

4 = Lawyer

5 = Consumer or non-health professional

primarysource.reportercountry

**string**

The name of the country from which the report was submitted.

reportduplicate

**list**

If a report is a duplicate or more recent version than a previously submitted report, this field will provide additional details on source provider.

reportduplicate.duplicatesource

**string**

The name of the organization providing the duplicate.

reportduplicate.duplicatenumb

**string**

The case identifier for the duplicate.

sender

**list**

Information on the organization sending the report.

sender.sendertype

**string**

The name of the organization sending the report. Because FDA is providing these reports to you, it will always appear as 2.

1 = Pharmaceutical Company

2 = Regulatory Authority

3 = Health Professional

4 = Regional Pharmacovigilance Center

5 = WHO Collaborating Center for International Drug Monitoring

6 = Other

sender.senderorganization

**string**

The name of the organization sending the report. Because FDA is providing these reports to you, it will always appear as FDA-Public Use.

receiver

**list**

Information on the organization receiving the report.

receiver.receivertype

**string**

The name of the organization receiving the report.

1 = Pharmaceutical Company

2 = Regulatory Authority

3 = Health Professional

4 = Regional Pharmacovigilance Center

5 = WHO Collaborating Center for International Drug Monitoring

6 = Other

receiver.receiverorganization

**string**

The name of the organization receiving the report.

**Patient**

Information about the patient in the adverse event report.

patient: {

"patientonsetage": "59",

"patientonsetageunit": "801",

"patientsex": "2",

"patientweight": "78",

"patientdeath": {

"patientdeathdate": "20030401",

"patientdeathdateformat": "102"

},

"drug": [

{

"actiondrug": "1",

"drugadditional": "1",

"drugcumulativedosagenumb": "4100",

"drugcumulativedosageunit": "003",

"drugdosageform": "Tablet",

"drugintervaldosagedefinition": "804",

"drugintervaldosageunitnumb": "1",

"drugrecurreadministration": "3",

"drugseparatedosagenumb": "1",

"drugstructuredosagenumb": "600",

"drugstructuredosageunit": "003",

"drugadministrationroute": "048",

"drugauthorizationnumb": "021223",

"drugbatchnumb": "020113A",

"drugcharacterization": "1",

"drugdoseagetext": "3.5 MG/KG, 1 IN 1 AS NECESSARY, INTRAVENOUS DRIP",

"drugenddate": "20020920",

"drugenddateformat": "102",

"drugindication": "RHEUMATOID ARTHRITIS",

"drugstartdate": "20020903",

"drugstartdateformat": "102",

"drugtreatmentduration": "1",

"drugtreatmentdurationunit": "804",

"medicinalproduct": "ASCORBIC ACID",

"openfda": {

"spl\_id": [

"f67ce1df-27ea-4c67-a8a3-daf3fb3b9a92",

"72133842-ac3f-4a39-a825-38e01930a0a7"

],

"product\_ndc": [

"0389-0486",

"67457-118",

"67457-303"

],

"route": [

"INTRAMUSCULAR",

"INTRAVENOUS",

"SUBCUTANEOUS"

],

"substance\_name": [

"ASCORBIC ACID"

],

"rxcui": [

"308395"

],

"spl\_set\_id": [

"a6c36a36-28ee-4a1b-86fe-98ef94064b68",

"d05200cb-cf29-4bc7-bf0c-b42ab2d20958"

],

"package\_ndc": [

"67457-118-50",

"0389-0486-50",

"67457-303-50"

],

"product\_type": [

"HUMAN PRESCRIPTION DRUG"

],

"generic\_name": [

"ASCORBIC ACID"

],

"manufacturer\_name": [

"The Torrance Company",

"Mylan Institutional LLC"

],

"brand\_name": [

"ASCORBIC ACID"

]

}

}

],

"reaction": [

{

"reactionmeddrapt": "Osteonecrosis of jaw",

"reactionmeddraversionpt": "16.1",

"reactionoutcome": "6"

},

{

"reactionmeddrapt": "HYPERTENSION"

},

{

"reactionmeddrapt": "POLYTRAUMATISM"

}

]

}

}

patient.patientonsetage

**string**

The age of the patient when the event first occured.

patient.patientonsetageunit

**string**

The unit of measurement for the patient.patientonsetage field.

800 = Decade

801 = Year

802 = Month

803 = Week

804 = Day

805 = Hour

patient.patientsex

**string**

The sex of the patient.

0 = Unknown

1 = Male

2 = Female

patient.patientweight

**string**

The weight of the patient expressed in kilograms.

patient.patientdeath

**list**

If the patient died, this section contains information about the death.

patient.patientdeath.patientdeathdate

**string**

Date that the patient died.

patient.patientdeath.patientdeathdateformat

**string**

Identifies the encoding format of the tient.patientdeath.patientdeathdate field. Always set to 102 (YYYYMMDD).

**Drugs**

This section contains information about the drugs listed in the adverse event report.

patient.drug

**list of objects**

Drugs known to be taken by the patient at the time of the adverse event.

patient.drug.actiondrug

**string**

Actions taken with the drug

1 = Drug withdrawn

2 = Dose reduced

3 = Dose increased

4 = Dose not changed

5 = Unknown

6 = Not applicable

patient.drug.drugadditional

**string**

Additional details about the circumstances surrounding the patient’s use of the drug.

patient.drug.drugcumulativedosagenumb

**string**

The cumulative dose taken until the first reaction was experienced.

patient.drug.drugcumulativedosageunit

**string**

The unit for drugcumulativedosagenumb

001 = kg kilogram(s)

002 = G gram(s)

003 = Mg milligram(s)

004 = μg microgram(s)

patient.drug.drugdosageform

**string**

The drug’s dosage form.

patient.drug.drugintervaldosagedefinition

**string**

The unit for the interval in patient.drug.drugintervaldosageunitnumb.

801 = Year

802 = Month

803 = Week

804 = Day

805 = Hour

806 = Minute

807 = Trimester

810 = Cyclical

811 = Trimester

812 = As Necessary

813 = Total

patient.drug.drugintervaldosageunitnumb

**string**

Number of units in patient.drug.drugintervaldosagedefinition

patient.drug.drugrecurreadministration

**string**

Whether the reaction occured on a readministration of the drug.

1 = Yes

2 = No

3 = Unknown

patient.drug.drugseparatedosagenumb

**string**

The number of separate dosages.

patient.drug.drugstructuredosagenumb

**string**

The number of doses.

patient.drug.drugstructuredosageunit

**string**

The unit for drugstructuredosagenumb

001 = kg kilogram(s)

002 = G gram(s)

003 = Mg milligram(s)

004 = μg microgram(s)

patient.drug.drugadministrationroute

The drug’s route of administration.

001 = Auricular (otic)

002 = Buccal

003 = Cutaneous

004 = Dental

005 = Endocervical

006 = Endosinusial

007 = Endotracheal

008 = Epidural

009 = Extra-amniotic

010 = Hemodialysis

011 = Intra corpus cavernosum

012 = Intra-amniotic

013 = Intra-arterial

014 = Intra-articular

015 = Intra-uterine

016 = Intracardiac

017 = Intracavernous

018 = Intracerebral

019 = Intracervical

020 = Intracisternal

021 = Intracorneal

022 = Intracoronary

023 = Intradermal

024 = Intradiscal (intraspinal)

025 = Intrahepatic

026 = Intralesional

027 = Intralymphatic

028 = Intramedullar (bone marrow)

029 = Intrameningeal

030 = Intramuscular

031 = Intraocular

032 = Intrapericardial

033 = Intraperitoneal

034 = Intrapleural

035 = Intrasynovial

036 = Intratumor

037 = Intrathecal

038 = Intrathoracic

039 = Intratracheal

040 = Intravenous bolus

041 = Intravenous drip

042 = Intravenous (not otherwise specified)

043 = Intravesical

044 = Iontophoresis

045 = Nasal

046 = Occlusive dressing technique

047 = Ophthalmic

048 = Oral

049 = Oropharingeal

050 = Other

051 = Parenteral

052 = Periarticular

053 = Perineural

054 = Rectal

055 = Respiratory (inhalation)

056 = Retrobulbar

057 = Sunconjunctival

058 = Subcutaneous

059 = Subdermal

060 = Sublingual

061 = Topical

062 = Transdermal

063 = Transmammary

064 = Transplacental

065 = Unknown

066 = Urethral

067 = Vaginal

patient.drug.drugauthorizationnumb

Drug authorization or application number.

patient.drug.drugbatchnumb

Drug product lot number.

patient.drug.drugcharacterization

Reported role of the drug in the adverse event.

1 = Suspect drug

2 = Concomitant drug

3 = Interacting drug

patient.drug.drugdosagetext

Additional detail about the dosage taken.

patient.drug.drugenddate

Date the patient ended taking the drug.

patient.drug.drugenddateformat

Identifies the encoding format of the patient.drug.drugenddateformat field. Always set to 102 (YYYYMMDD).

patient.drug.drugindication

Indication for use in the case.

patient.drug.drugstartdate

Date the patient began taking the drug.

patient.drug.drugstartdateformat

Identifies the encoding format of the patient.drug.drugstartdate field. Always set to 102 (YYYYMMDD).

patient.drug.drugtreatmentduration

The length of time the patient was using the drug.

patient.drug.drugtreatmentdurationunit

The unit for patient.drug.drugtreatmentduration

801 = Year

802 = Month

803 = Week

804 = Day

805 = Hour

806 = Minute

patient.drug.medicinalproduct

Valid Trade name of the product

**openFDA fields**

openfda

**list**

For all fields in openfda, see the [API Basics](https://open.fda.gov/api/reference/#openfda-fields) reference guide.

Different datasets use different drug identifiers—brand name, generic name, NDA, NDC, etc. It can be difficult to find the same drug in different datasets. And some identifiers, like pharmacologic class, are useful search filters but not available in all datasets.

OpenFDA features harmonization of drug identifiers, to make it easier to connect adverse event report records to other drug information. Drug products that appear in FAERS records are joined to the NDC dataset first on brand name, and if there is no brand name, on generic name. If that is succesful, further links are established to other datasets. The linked data is listed as an openfda annotation in the patient.drug section of a result.

Roughly 86% of adverse event records have at least one openfda section. Because the harmonization process requires an exact match, some drug products cannot be harmonized in this fashion—for instance, if the drug name is misspelled. Some drug products will have openfda sections, while others will never, if there was no match during the harmonization process.

Important note about openfda fields

A single drug product listed in an adverse event report may have multiple associated manufacturer names, NDCs, and SPLs in a corresponding openfda section. That is because the drug may have multiple manufacturers, packagers, dosage forms, etc. Their inclusion in the openfda section does not mean that they had any connection to the adverse event. The ordering of data in openfda fields is not significant.

**Reactions**

patient.reaction.reactionmeddrapt

[MedDRA](http://www.meddra.org/) [External link icon](http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)term(s) for the reaction(s). Note that these terms are encoded in British English. For instance, “diarrhea” is recorded as “diarrohea.”

patient.reaction.reactionmeddraversionpt

The [MedDRA](http://www.meddra.org/) [External link icon](http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)version that patient.reaction.reactionmeddrapt uses.

patient.reaction.reactionoutcome

Outcome of the reaction or event at the time of last observation.

1 = Recovered/resolved.

2 = Recovering/resolving.

3 = Not recovered/not resolved.

4 = Recovered/resolved with sequelae.

5 = Fatal.

6 = Unknown.