



“FDA Adverse Event Reporting System (FAERS) Public Dashboard”

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DISCLAIMER



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LEARNING OBJECTIVES



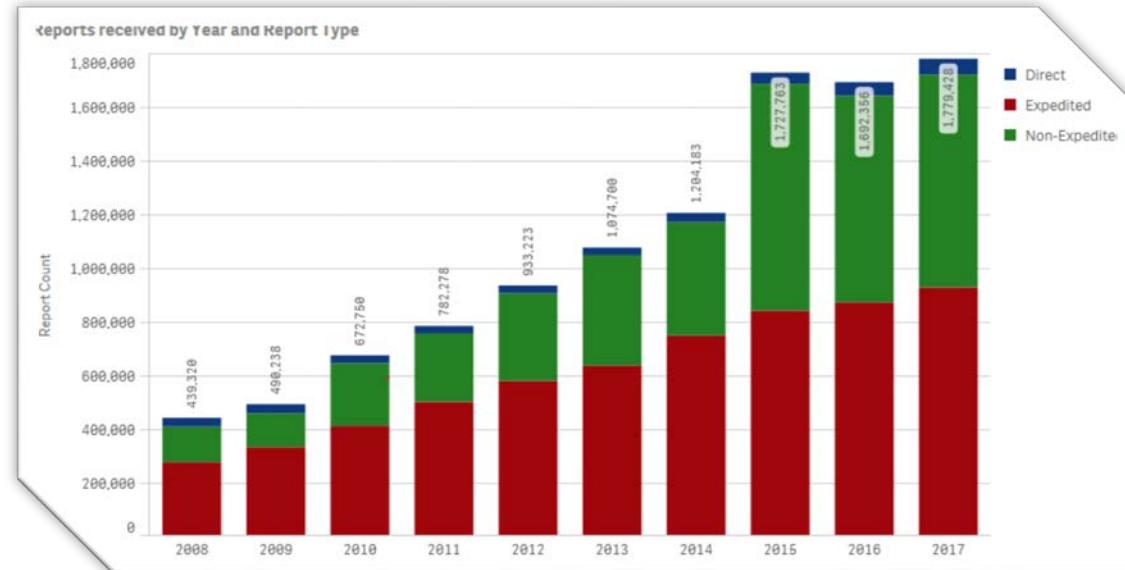
- Describe the FAERS public database
- Demonstrate how to use the FAERS public dashboard to view adverse event reporting metrics
- Illustrate use of FAERS public dashboard to view adverse event information on a specific product

BACKGROUND



The FDA Adverse Events Reporting System (FAERS) is a database that contains spontaneous adverse event reports that are submitted to FDA from the product manufacturer or directly from the consumer, healthcare professional, or other reporter. The database supports the FDA's post marketing safety surveillance program for drug and therapeutic biologic products.

The database consists of more than fourteen (14) million reports since 1969 to August 2017. Each year, FDA receives over one (1) million adverse events and medication error reports associated with the use of drug or biologic products. Existence of a report does not establish causation.



OBJECTIVE



FDA provides information to the public in an accessible and transparent manner. This new FAERS dashboard gives the public and industry a more user friendly platform for accessing FAERS reports and making adverse event data more accessible and transparent.

FAERS data outlets for public:



Open FDA

JSON File(s)

The screenshot shows the QDE page with a large blue banner at the top stating "Text/ASCII Files and XML File(s)". Below the banner, there are three download links: "JSON File", "XML File", and "CSV File". The page also includes a brief description of what QDE is and how to use it.

FAERS Quarterly Data Extracts (QDE)



Easy Interactive Access

FAERS Public Dashboard

The FAERS Public Dashboard is an interactive application, which enables the user to search for information related to adverse events reported to the FDA by the pharmaceutical industry, healthcare providers and consumers.

KEY POINTS TO CONSIDER



Data Quality

- There are many instances of duplicative reports and some reports do not contain all the necessary information.

Existence of a report does not establish causation

- There is no certainty that a suspected drug caused the adverse events.
- Adverse events may have been related to the underlying disease being treated, or caused by some other drug being taken concurrently, or occurred for other reasons.
- The information in these reports reflects only the reporter's observations and opinions.

Information in reports has not been verified

- Submission of a report does not mean that the information included in it has been medically confirmed.

KEY POINTS TO CONSIDER



- ❑ **Rates of occurrence cannot be established with reports**
 - The number of adverse events should not be used to determine the likelihood of a side effect occurring.
 - Factors such as the time a product has been marketed and publicity can influence reporting.
- ❑ **Patients should talk to their doctor** before stopping or changing how they take their medications
- ❑ **Patient Outcomes received in FAERS**
 - A reported serious outcomes does not necessarily mean that the suspect product(s) named in the report was the cause of these outcomes.



FAERS data by themselves are not an indicator that the drug is causing the reported adverse events.

SPONTANEOUS REPORTS

- A communication from an individual (e.g., health care professional, consumer) to a company or regulatory authority
- Describes a suspected adverse event(s)
- Passive and voluntary reports

FACTORS AFFECTING REPORTING

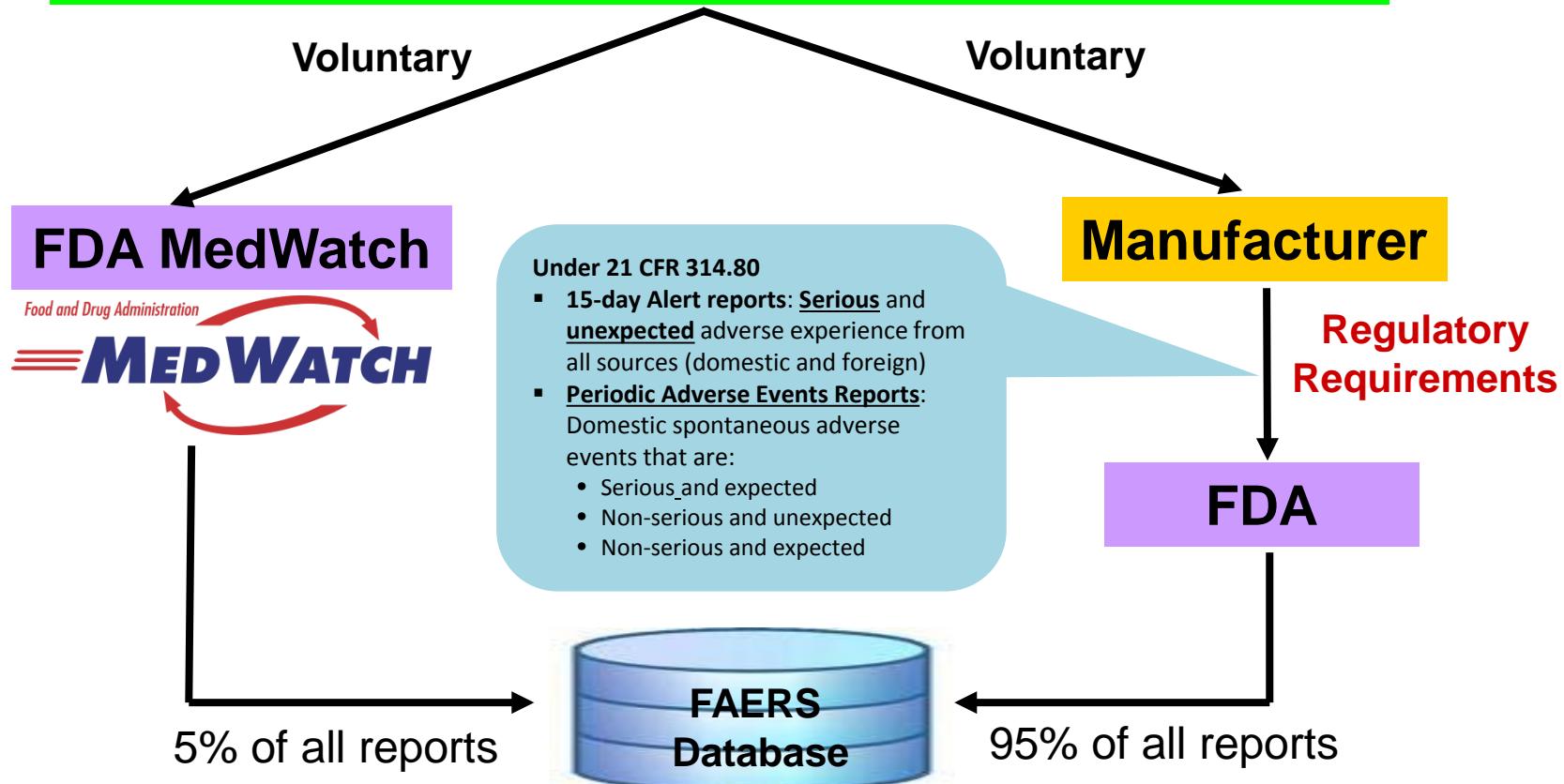
FDA

- Media attention
- Litigation (class action lawsuits)
- Nature of the adverse event
- Type of drug product and indication
- Length of time on market
- Extent and quality of manufacturer's surveillance system
- Prescription or over-the-counter (OTC) product status
- Reporting regulations

HOW POSTMARKETING REPORTS GET TO FDA



Patients, consumer, and healthcare professionals



FAERS STRENGTHS

- Includes all U.S. marketed products
- Includes all uses
- Includes broad patient populations:
 - elderly, children, pregnant women, comorbidities
- Especially good for events with a rare background rate
- Useful for events that occur shortly after exposure
- Detection of events not seen in clinical trials (“signal generation”)
- Identification of reporting trends, possible risk factors, at risk populations, and other clinically significant emerging safety concerns

FAERS IS LESS USEFUL FOR

- Events with high background rates
- Worsening of pre-existing disease
- Issue that goes beyond data captured from the MedWatch Form or electronic reporting
- Comparative incidence rates
- Comparing drugs in the same class
- Adverse events that could also be manifestations of the disease for which the drug is indicated



FAERS PUBLIC DASHBOARD

LAUNCH FAERS PUBLIC DASHBOARD

<https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070093.htm>

The screenshot shows the FDA Adverse Events Reporting System (FAERS) Public Dashboard. The page has a dark blue header with the FDA logo and navigation links for Home, Food, Drugs, Medical Devices, etc. Below the header, there's a breadcrumb trail: Home > Drugs > Guidance, Compliance & Regulatory Information > Surveillance > FDA Adverse Events Reporting System (FAERS). The main content area is titled "FDA Adverse Events Reporting System (FAERS) Public Dashboard". It features a summary of the tool's purpose, limitations, and key findings. A sidebar on the left lists links such as "FDA Adverse Event Reporting System (FAERS) Latest Quarterly Data Files", "FDA Adverse Events Reporting System (FAERS) Public Dashboard", "Potential Signals of Serious Risks/New Safety Information Identified from the FDA Adverse Event Reporting System (FAERS)", and "FDA Adverse Events Reporting System (FAERS) Electronic Submissions". At the bottom, there's a call-to-action button: "Launch the FDA Adverse Events Reporting System (FAERS) Public Dashboard".

DISCLAIMER

FDA

Disclaimer

Each year, the FDA receives over one million adverse event and medication error reports associated with the use of drug or biologic products. The FDA uses these reports to monitor the safety of drug and biological products. The FDA Adverse Event Reporting System (FAERS) database houses reports submitted to the FDA by drug manufacturers (who are required to submit these reports to FDA) and others such as health care professionals and consumers. 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.

Although these reports are a valuable source of information, this surveillance system has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified information. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to potential under-reporting of events and lack of information about frequency of use. Because of this, FAERS data comprise only one part of the FDA's important post-market surveillance data and the information on this website does not confirm a causal relationship between the drug product and the reported adverse event(s).

- Consumers should not stop or change medication without first consulting with a health care professional.
- The FAERS web search feature is limited to adverse event reports between 1969 and the most recent quarter for which data are available.
- Data submitted to the FAERS system will be made available through the new querying tool on a quarterly basis.
- FAERS data alone cannot be used to establish rates of events, evaluate a change in event rates over time or compare event rates between drug products. The number of reports cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with drug products.
- Confirming whether a drug product actually caused a specific event can be difficult based solely on information provided in a given report.
- FAERS data do not represent all known safety information for a reported drug product and should be interpreted in the context of other available information when making drug-related or treatment decisions.
- Variations in trade, product, and company names affect search results. Searches only retrieve records that contain the search term(s) provided by the requester.

Importantly, safety reports submitted to FDA do not necessarily reflect a conclusion by FDA that the information in the reports constitutes an admission that the drug caused or contributed to an adverse event. Individual FAERS reports for a given product can be requested by submitting a Freedom of Information Act (FOIA) request at:

<http://www.fda.gov/regulatoryinformation/foi/howtomakeafoiarequest/default.htm>

Accept

Do Not Accept

Click on "Accept" to accept
disclaimer and view
information on the
dashboard

QUESTION 1

Select all the key points to consider while viewing the contents of the dashboard

- a. Quality of adverse event data
- b. Existence of a report does not establish causation
- c. Information in reports has not been verified
- d. Rates of occurrence cannot be established with reports
- e. Patients should talk to their doctor before stopping or changing their medication
- f. All of the above

QUESTION 2

Dr. Doe a private physician views adverse event data on a product. Looking at the volume of the data set for that product he concludes that the product is risky to prescribe.

Did Dr. Doe make an informed decision?

- a. Yes
- b. No

QUESTION 2

Dr. Doe a private physician views adverse event data on a product. Looking at the volume of the data set for that product he concludes that the product is risky to prescribe.

Did Dr. Doe make an informed decision?

- a. Yes
- b. No

- Existence of a report does not establish causation
- Rates of occurrence cannot be established with reports

KEY PARTS OF DASHBOARD

Filter panel



Navigation panel



Count panel



KEY PARTS OF DASHBOARD



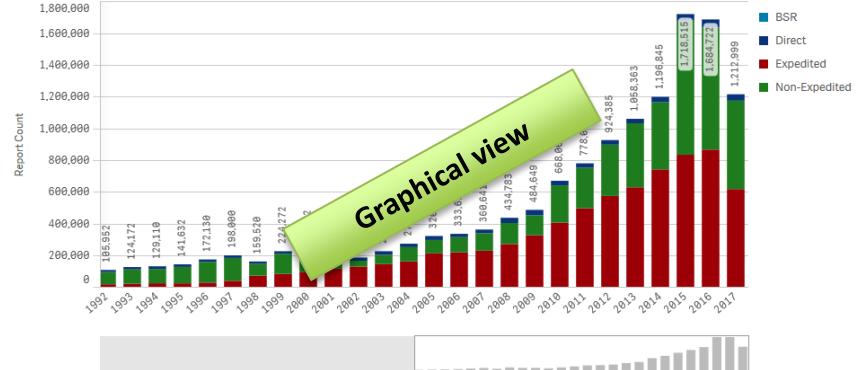
Data panel

Reports received by Year and Report Type

	Year ▾	Category ▾	Total Reports	Expedited	Non-Expedited	Direct	BSR
Total Reports	14,160,191	7,437,939	615,558	49,383	45,852	41,539	873
2017	1,212,999	615,558	-	-	-	-	-
2016	1,684,722	864,309	-	-	-	-	-
2015	1,718,515	831,177	45,852	-	-	-	-
2014	1,196,845	-	423,150	34,114	-	-	-
2013	1,058,363	-	403,368	28,303	-	-	-
2012	924,385	-	323,059	28,866	-	-	-
2011	778,724	-	255,058	27,995	-	-	-
2010	664,418	-	204,586	234,578	28,902	-	-
2009	484,418	-	324,421	126,138	34,890	-	-
2008	434,783	-	269,298	132,659	32,826	-	-
2007	360,641	-	227,294	110,389	22,958	-	-
2006	333,629	-	217,213	95,525	20,891	-	-
2005	320,016	-	210,363	84,472	25,175	-	6
2004	271,418	-	160,008	89,833	21,572	-	5
2003	222,444	-	140,750	60,601	22,070	-	14

Tabular view

Reports received by Year and Report Type



Graphical view

Page help panel

This page displays the number of adverse event reports received by FDA for drugs and therapeutic biologic products by the following Report Types.

- Direct Reports are voluntarily submitted directly to FDA through the MedWatch program by consumers and healthcare professionals.
- Mandatory Reports are submitted by manufacturers and are categorized as:
 - i. Expedited reports that contain at least one adverse event that is not currently described in the product labeling and for which the patient outcome is serious, or
 - ii. Non-expedited reports that do not meet the criteria for expedited reports, including cases that are reported as Serious and expected, Non-serious and unexpected and Non-serious and expected.

Describes the details of data displayed on the page

MAIN DASHBOARD PAGE



Main Dashboard Page Selected filter criteria

No selections applied

FDA Adverse Events Reporting System (AERS) Public Dashboard

Home Q Search for Products

Total Reports **14,160,191**

Serious Reports (excluding death) **8,072,400**

Death Reports **1,420,885**

Provides an option to search adverse event by product

Displays counts of all death reports

View Disclaimer

Report an adverse event via a web portal

Frequently Asked Questions

U.S. FOOD & DRUG ADMINISTRATION

Reports received by Year and Report Type

Year ▾ Category ▾

	Total Reports	Expedited	Non-Expedited	Direct	BSR
Total Reports	14,160,191	7,437,939	5,981,598	739,781	873
2017	1,212,999	615,558	557,058	40,383	-
2016	1,684,722	864,309	769,534	50,879	-
2015	1,718,515	831,924	15,052	41,539	-
2014	1,196,845	739,581	150	34,114	-
2013	1,058,363	626,602	103,368	28,303	-
2012	924,385	520,000	323,059	28,866	-
2011	778,014	420,000	255,058	27,995	-
2010	668,066	345,586	234,578	28,902	-
2009	484,000	324,421	126,138	34,090	-
2008	434,000	269,298	132,659	32,826	-
2007	360,641	227,294	110,389	22,958	-
2006	333,629	217,213	95,525	20,891	-
2005	320,016	210,363	84,472	25,175	6
2004	271,418	160,008	89,833	21,572	5
2003	229,444	140,750	60,601	20,070	14

Tabular view

Reports received by Year and Report Type

Report Count

Graphical view

Data as of August 31, 2017

This page displays the number of adverse event reports received by FDA for drugs and therapeutic biologic products by the following Report Types.

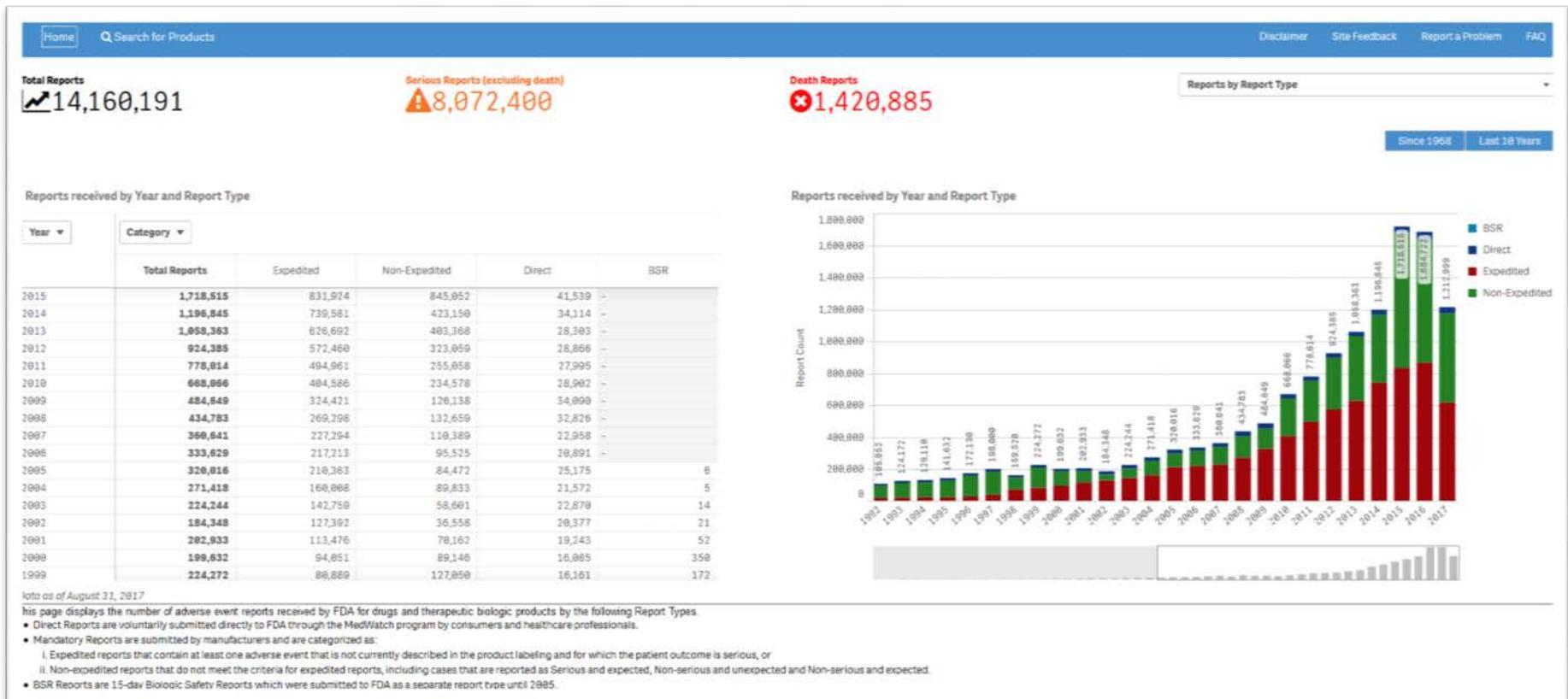
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 - ii. Non-expedited reports that do not meet the criteria for expedited reports, including cases that are reported as Serious and expected, Non-serious and unexpected and Non-serious and expected.
- BSR Reports are 15-day Biologic Safety Reports which were submitted to FDA as a separate report type until 2005.

Describes the details of data displayed on the page

MAIN DASHBOARD

REPORTS BY REPORT TYPE

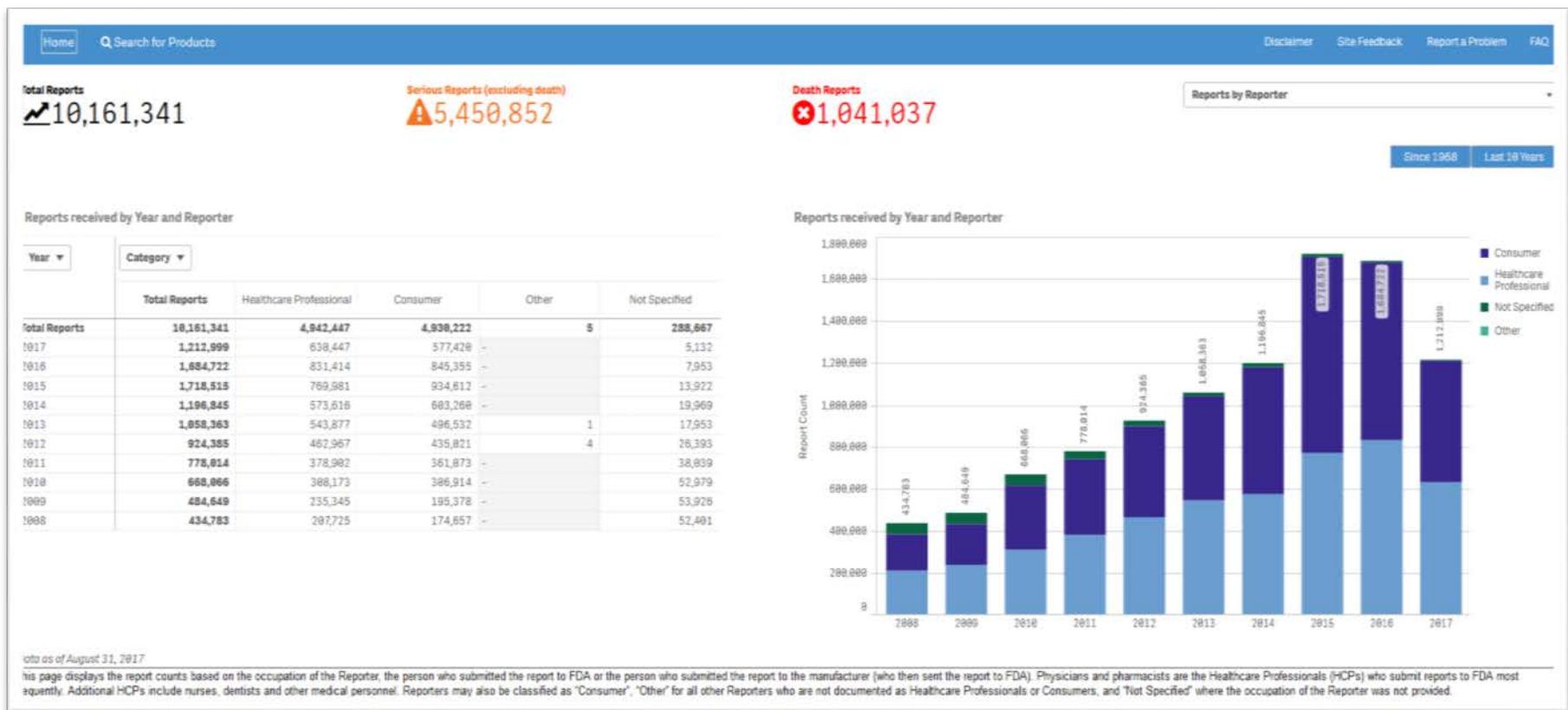
Displays the number of adverse event reports received by FDA for drugs and therapeutic biologic by report type



MAIN DASHBOARD

REPORTS BY REPORTER

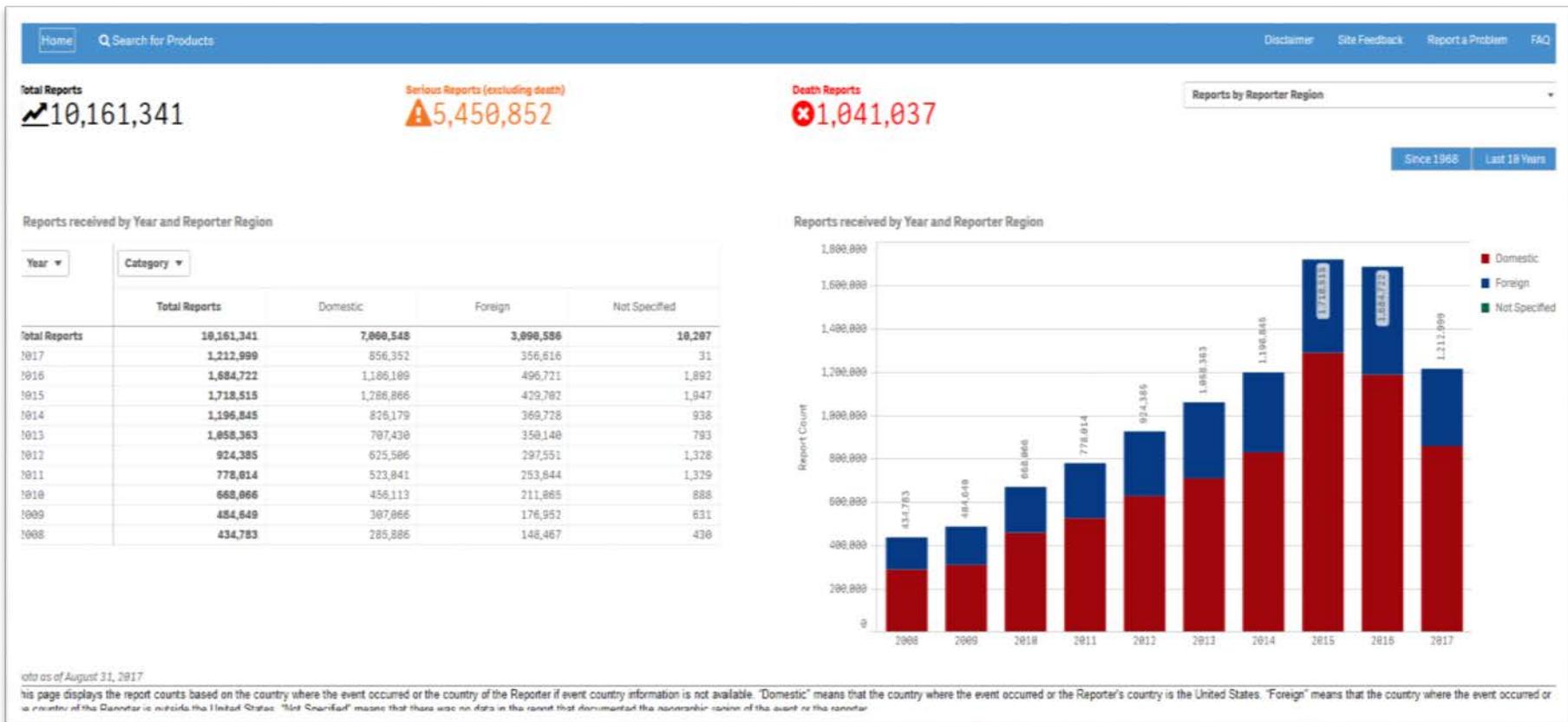
Displays the number of adverse event reports received by FDA for drugs and therapeutic biologic by type of reporter



MAIN DASHBOARD

REPORTS BY REPORTER REGION

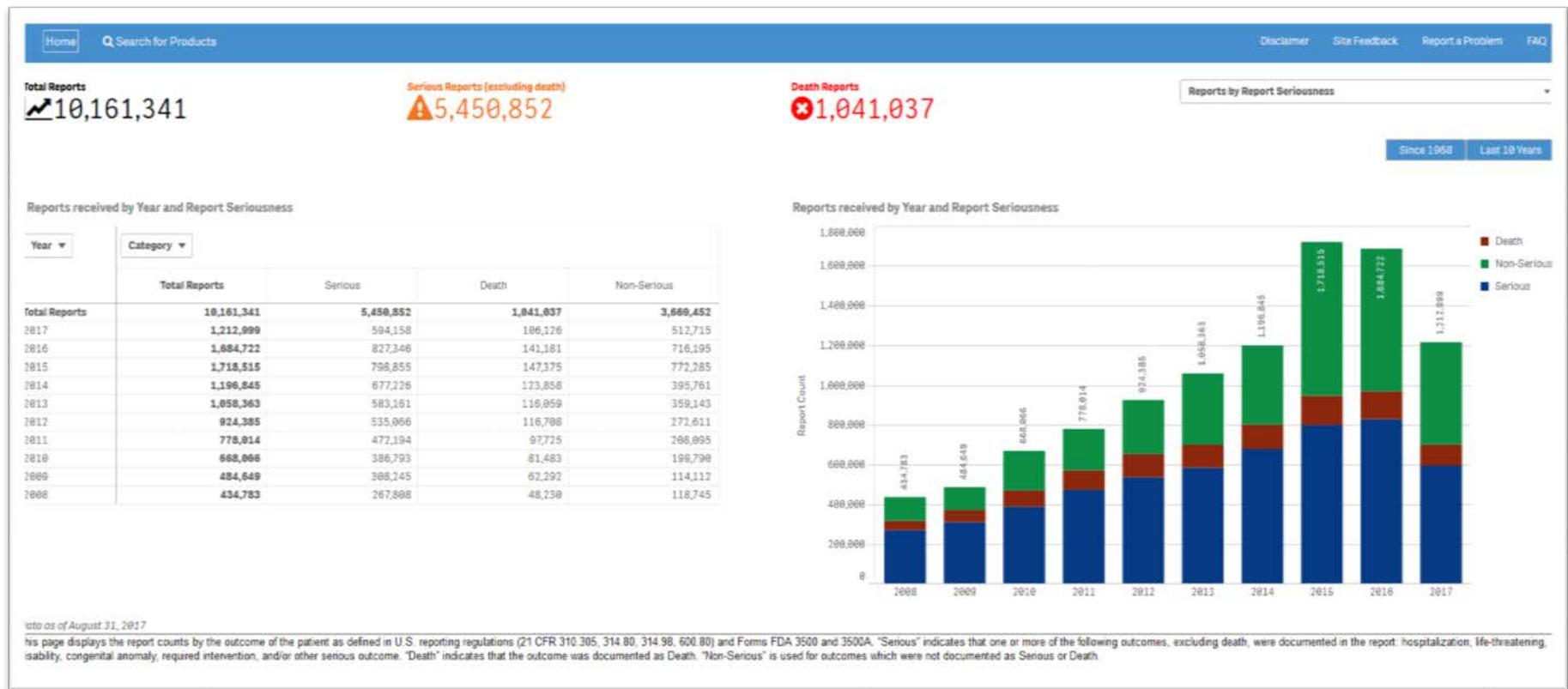
Displays the number of adverse event reports received by FDA for drugs and therapeutic biologic based on the country where the event occurred.



MAIN DASHBOARD

REPORTS BY REPORT SERIOUSNESS

Displays the number of adverse event reports received by FDA for drugs and therapeutic biologic by outcome of the patient as defined in regulations (21CFR 310.305, 314.80, 314.98, 600.80) and FDA MedWatch forms (3500 and 3500B)



QUESTION 3

The report counts on the main dashboard page are the counts of reports that include initials and follow-ups

- a. True
- b. False

QUESTION 4

The main dashboard page displays report counts on which of the following criteria

- a. Report Type
- b. Reporter
- c. Reporter Region
- d. Report Seriousness
- e. All of the above



SEARCH FOR PRODUCTS

SEARCH FOR PRODUCTS



Search for products

No selections applied

FDA Adverse Events Reporting System (FAERS) Public Dashboard

Home Search for Products Disclaimer Site Feedback Report a Problem FAQ

Total Reports **14,160,191**

Serious Reports (excluding death) **8,072,400**

Death Reports **1,420,885**

Reports by Report Type Since 1968 Last 10 Years

Reports received by Year and Report Type

Year	Category	Total Reports	Expedited	Non-Expedited	Direct	BSR
Total Reports		14,160,191	7,437,939	5,981,598	739,781	873
2017		1,212,999	615,558	557,058	48,383	-
2016		1,684,722	864,389	769,534	58,879	-
2015		1,718,515	831,924	845,852	41,539	-
2014		1,196,845	739,581	423,158	34,114	-
2013		1,058,363	626,692	483,368	28,303	-
2012		924,385	572,466	323,059	28,866	-
2011		778,014	494,961	255,058	27,995	-
2010		668,066	484,586	234,578	28,902	-
2009		484,649	324,421	176,138	34,098	-
2008		434,783	269,298	132,659	32,826	-
2007		366,641	227,294	118,389	22,958	-
2006		333,629	217,213	95,525	28,891	-
2005		320,016	210,363	84,472	25,175	6
2004		271,418	160,088	89,833	21,572	5
2003		224,244	142,759	58,601	22,878	14
2002		184,348	127,392	36,558	28,377	21

Data as of August 31, 2017

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- BSR Reports are 15-day Biologic Safety Reports which were submitted to FDA as a separate report type until 2005.

Reports received by Year and Report Type

Year	BSR	Direct	Expedited	Non-Expedited	Total
1992	0	0	0	8	8
1993	0	0	0	124,172	124,172
1994	0	0	0	124,118	124,118
1995	0	0	0	141,632	141,632
1996	0	0	0	172,130	172,130
1997	0	0	0	198,080	198,080
1998	0	0	0	198,420	198,420
1999	0	0	0	224,472	224,472
2000	0	0	0	199,632	199,632
2001	0	0	0	202,893	202,893
2002	0	0	0	232,344	232,344
2003	0	0	0	271,418	271,418
2004	0	0	0	310,816	310,816
2005	0	0	0	333,629	333,629
2006	0	0	0	366,641	366,641
2007	0	0	0	434,783	434,783
2008	0	0	0	484,649	484,649
2009	0	0	0	561,086	561,086
2010	0	0	0	668,066	668,066
2011	0	0	0	778,014	778,014
2012	0	0	0	924,385	924,385
2013	0	0	0	1,086,363	1,086,363
2014	0	0	0	1,196,846	1,196,846
2015	0	0	0	1,212,999	1,212,999
2016	0	0	0	1,684,722	1,684,722
2017	0	0	0	1,718,515	1,718,515

SEARCH FOR PRODUCTS

A screenshot of the FDA Adverse Events Reporting System (FAERS) Public Dashboard. At the top, there is a dark header bar with the text "No selections applied". Below it is a light gray header bar with the text "FDA Adverse Events Reporting System (FAERS) Public Dashboard". On the far right of this bar is the FDA logo. The main content area has a blue header bar with links for "Home", "Search for Products" (which is highlighted with a magnifying glass icon), "Disclaimer", "Site Feedback", "Report a Problem", and "FAQ". Below these bars, there is a search form titled "Search for a Product" with a search input field containing a magnifying glass icon. A large green callout bubble with a black border points from the bottom right towards the search input field. Inside the bubble, the text reads: "Search for a product (brand name) or active ingredient (generic name). This field provides a smart search capability".

No selections applied

FDA Adverse Events Reporting System (FAERS) Public Dashboard

Home Search for Products Disclaimer Site Feedback Report a Problem FAQ

Search for a Product

Search for a product (brand name) or active ingredient (generic name). This field provides a smart search capability

SEARCH FOR PRODUCTS



No selections applied

FDA Adverse Events Reporting System (FAERS) Public Dashboard

Home Disclaimer Site Feedback Report a Problem FAQ

Field to search for both brand name and generic name products. Typing three letters provides all match texts highlighted in yellow.

Select “Amlodipine Besylate”

P (in green color) – Brand Name of the product

G (in orange color) – Generic Name of the product

Search for a Product

- ami
- Amlodipine
- Amlodipine And Atorvastatin
- Amlodipine And Olmesartan Medoxomil
- Amlodipine And Valsartan
- Amlodipine Besylate**
- Amlodipine Besylate And Atorvastatin Calcium
- Amlodipine Besylate And Benazepril Hydrochloride
- Amlodipine Besylate And Valsartan
- Amlodipine Besylate/Atorvastatin Calcium

QUESTIONS 5

Rebecca is a researcher at a university and is currently researching on a recently approved drug with NDA number 209310 (i.e. SINUVA – brand name, MOMETASONE FUROATE – generic name). She is exploring FAERS public dashboard to find information on the product of interest.

Select the applicable options for her to perform a search for product details?

- a. By NDA number
- b. By Brand Name
- c. By Generic Name
- d. By Brand Name or Generic Name
- e. None of the above

SEARCH PRODUCT RESULT



Filter applied for the selected product

Total number of latest version of the reports listed

Selected product displayed

List of reports available

FDA Adverse Events Reporting System (FAERS) Public Dashboard

U.S. FOOD & DRUG ADMINISTRATION

AMLODIPINE BESYLATE

Total Cases **47,204**

serious Cases [including deaths] **41,047**

Death-Cases **6,608**

Case Count by Received Year

Category	Q.	Number of Cases	Percentage
2017		3,352	7.18%
2016		4,974	8.53%
2015		3,771	7.88%
2014		3,333	7.06%
2013		3,496	7.41%
2012		2,553	5.41%
2011		2,342	4.96%
2010		2,318	4.91%
2009		1,323	2.80%
2008		961	2.04%
2007		1,821	2.18%
2006		938	1.97%
2005		892	1.89%
Totals		47,204	100.00%

Case Count by Received Year

Cases by Received Year

Cases by Reaction

Cases by Age Group

Cases by Sex

Cases by Reporter Type

Data as of August 31, 2017

This page displays the number of cases identified for the product of interest by 'Received Year'. 'Received Year' is the year the case was received by the FDA.

DEMOGRAPHICS



Filters applied for years

Drag the mouse to select years or by individual clicks

FDA Adverse Events Reporting System (FAERS) Public Dashboard

U.S. FOOD & DRUG ADMINISTRATION

Home Demographics Reaction Group Reaction Listing of Cases Disclaimer Site Feedback Report a Problem Amlodipine Besylate

AMLODIPINE BESYLATE

Total Cases 3,352

Serious Cases (including deaths) 2,761

Death Cases 619

Case Count by Received Year

Category	Number of Cases	Percentage
2017	3,352	16.33%
2016	4,074	19.85%
2015	3,721	18.13%
2014	3,333	16.24%
2013	3,496	17.03%
2012	2,553	12.44%
Totals	20,529	100.00%

Cases by Received Year

Received Year	Number of Cases
2017	3,352
2016	4,074
2015	3,721
2014	3,333
2013	3,496
2012	2,553
2011	2,342
2010	2,318
2009	1,323
2008	961
2007	1,021
2006	938
2005	892
2004	714

Data as of August 31, 2017
This page displays the number of cases identified for the product of interest by "Received Year". "Received Year" is the year the case was received by the FDA.

DEMOGRAPHICS



Years filter applied from 2012 to 2017

Total number of cases for the 2012 to 2017

FDA Adverse Events Reporting System (FAERS) Public Dashboard

U.S. FOOD & DRUG ADMINISTRATION

Home Demographics Reaction Group Reaction Listing of Cases Disclaimer Site Feedback Report a Problem FAQ Amlodipine Besylate

AMLODIPINE BESYLATE

Total Cases 20,529

Serious Cases (including deaths) 16,459

Death Cases 3,146

Cases by Received Year

Case Count by Received Year

Category	Number of Cases	Percentage
2017	3,352	16.33%
2016	4,074	19.85%
2015	3,721	18.13%
2014	3,333	16.24%
2013	3,496	17.03%
2012	2,553	12.44%
Totals	20,529	100.00%

Data as of August 2017. This page displays the number of cases identified for the product of interest by "Received Year". "Received Year" is the year the case was received by the FDA.

Case by years - tabular view

Case by years - graphical view

DEMOGRAPHICS



Years filter applied from 2012 to 2017

Total number of cases for the 2012 to 2017

Cases by Reactions

FDA Adverse Events Reporting System (FAERS) Public Dashboard

U.S. FOOD & DRUG ADMINISTRATION

AMLODIPINE BESYLATE

Total Cases 20,529

Serious Cases (including deaths) 16,459

Death Cases 3,146

Cases by Reaction

Case Count by Reaction

Category	Number of Cases	Percentage
Completed Suicide	1,702	8.29%
Hypotension	1,692	8.24%
Dizziness	1,130	5.50%
Drug Hypersensitivity	1,092	5.32%
Toxicity To Various Agents	1,089	5.30%
Drug Interaction	957	4.66%
Drug Ineffective	917	4.47%
Headache	894	4.35%
Dyspnoea	884	4.31%
Overdose	830	4.04%
Fatigue	816	3.97%
Malaise	761	3.71%
Acute Kidney Injury	734	3.58%
Totals	20,529	100.00%

Data as of August 31, 2017

This page displays the number of cases identified for the product of interest by "Reaction". "Reaction" is the suspected side effect (also known as adverse event or adverse drug reaction) reported by the reporter and is based on the MedDRA dictionary Preferred Term (PT). A "Reaction" is a unique medical condition, sign, disease, diagnosis, therapeutic indication, investigation, surgical or medical procedure, etc. A case may contain more than one "Reaction".

Reactions listed in descending order

Scrollbar to view all reactions

Reaction	Number of Cases
Completed Suicide	1,702
Hypotension	1,692
Dizziness	1,130
Drug Hypersensitivity	1,092
Toxicity To Various Agents	1,089
Drug Interaction	957
Drug Ineffective	917
Headache	894
Dyspnoea	884
Overdose	830
Fatigue	816
Malaise	761
Acute Kidney Injury	734
Intentional Overdose	734

DEMOGRAPHICS



Years filter applied from 2012 to 2017

Total number of cases for the 2012 to 2017

Cases by Age Group

FDA Adverse Events Reporting System (FAERS) Public Dashboard

Search Term Amlodipine Besylate Received Year 6 of 59

Home Demographics Reaction Group Reaction Listing of Cases Disclaimer Site Feedback Report a Problem FAQ Amlodipine Besylate

FDA U.S. FOOD & DRUG ADMINISTRATION

AMLODIPINE BEZYLATE



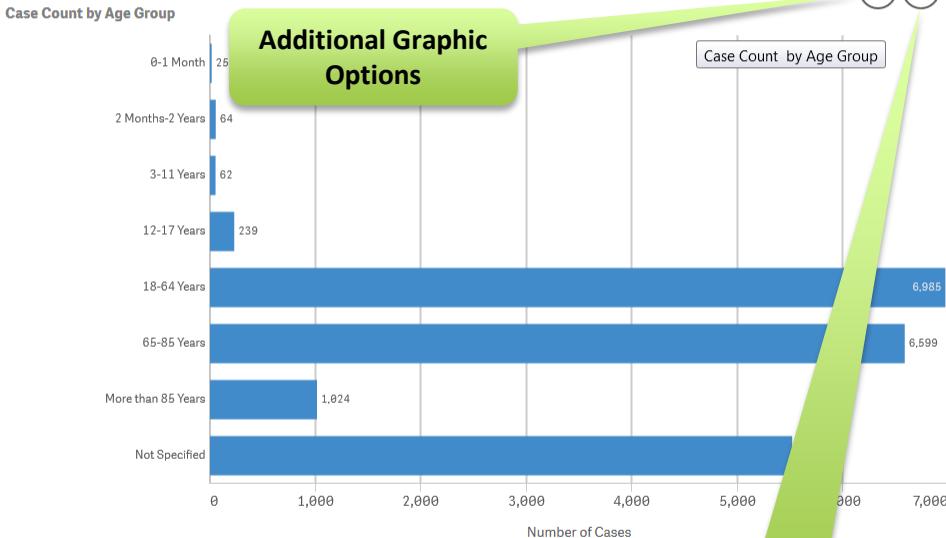
Total Cases
20,529

Serious Cases (including deaths)
16,459

Death Cases
3,146

Cases by Age Group

Category	Number of Cases	Percentage
0-1 Month	25	0.12%
2 Months-2 Years	64	0.31%
3-11 Years	62	0.30%
12-17 Years	239	1.16%
18-64 Years	6,985	34.03%
65-85 Years	6,599	32.14%
More than 85 Years	1,024	4.99%
Not Specified	5,531	26.94%
Totals	20,529	100.00%



Data as of August 31, 2017

This page displays the number of cases identified for the product of interest by the reported age of the patient. "Not Specified" indicates the patient's age was not reported.

Click to expand the view

DEMOGRAPHICS



Years filter applied from 2012 to 2017

Total number of cases for the 2012 to 2017

Cases by Sex

FDA Adverse Events Reporting System (FAERS) Public Dashboard

FDA U.S. FOOD & DRUG ADMINISTRATION

Home Demographics Reaction Group Reaction Listing of Cases Disclaimer Site Feedback Report a Problem FAQ Amlodipine Besylate

AMLODIPINE BESYLATE



Total Cases
20,529

Serious Cases (including deaths)
16,459

Death Cases
3,146

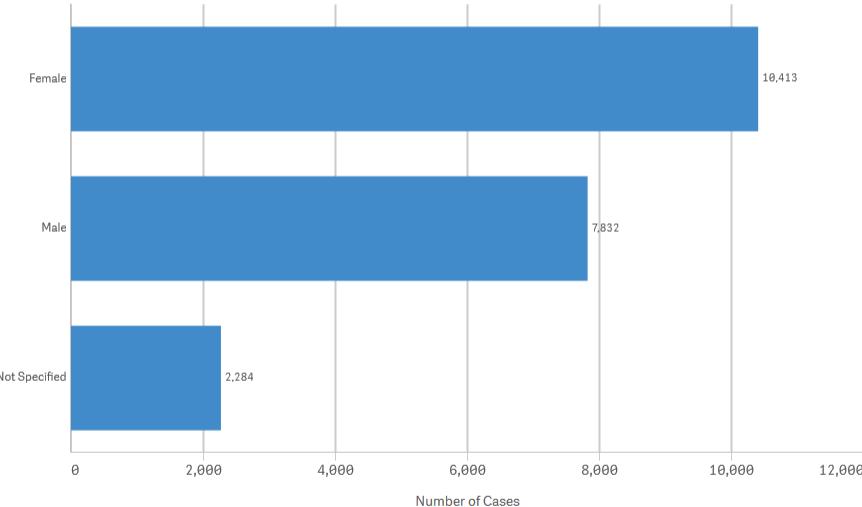
Cases by Sex



Case Count by Sex

Category	Number of Cases	Percentage
Female	10,413	50.72%
Male	7,832	38.15%
Not Specified	2,284	11.13%
Totals	20,529	100.00%

Case Count by Sex



Data as of August 31, 2017

This page displays the number of cases identified for the product of interest by sex. "Not Specified" indicates the patient's sex was not reported.

DEMOGRAPHICS



Years filter applied from 2012 to 2017

Total number of cases for the 2012 to 2017

Cases by Reporter Type

FDA Adverse Events Reporting System (FAERS) Public Dashboard

Home Demographics Reaction Group Reaction Listing of Cases Disclaimer Site Feedback Report a Problem FAQ Amlodipine Besylate

AMLODIPINE BESYLATE

Total Cases 20,529

Serious Cases (including deaths) 16,459

Death Cases 3,146

Cases by Reporter Type

Category	Number of Cases	Percentage
Healthcare Professional	13,273	64.65%
Consumer	6,816	33.20%
Not Specified	440	2.14%
Totals	20,529	100.00%

Case Count by Reporter

Reporter Type	Number of Cases
Healthcare Professional	13,273
Consumer	6,816
Not Specified	440

Data as of August 31, 2017

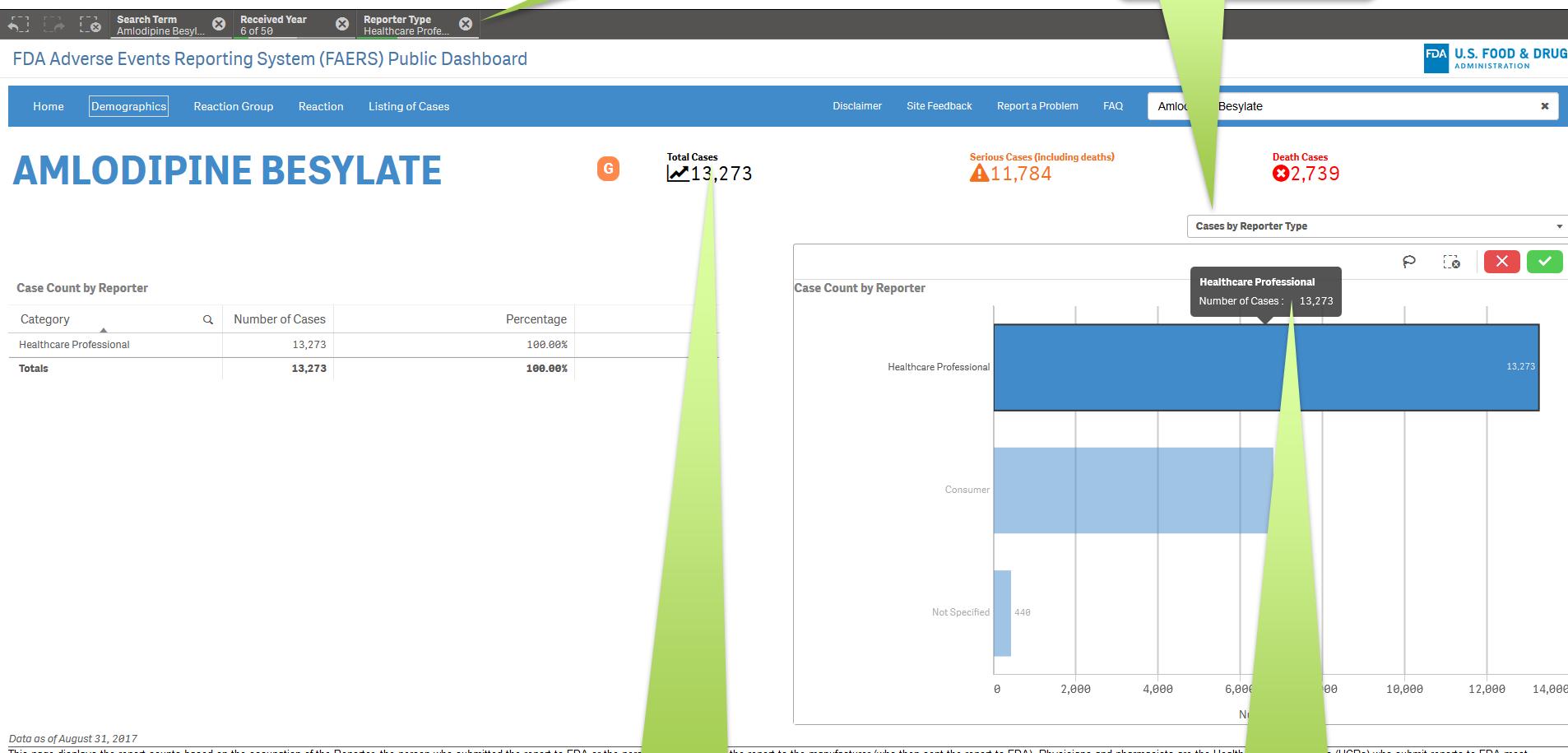
This page displays the report counts based on the occupation of the Reporter, the person who submitted the report to FDA or the person who submitted the report to the manufacturer (who then sent the report to FDA). Physicians and pharmacists are the Healthcare Professionals (HCPs) who submit reports to FDA most frequently. Additional HCPs include nurses, dentists and other medical personnel. Reporters may also be classified as "Consumer", "Other" for all other Reporters who are not documented as Healthcare Professionals or Consumers, and "Not Specified" where the occupation of the Reporter was not provided.

DEMOGRAPHICS



Reporter type filter
“Healthcare Professional” applied

Cases by Reporter Type



Total number of cases based on applied filter

Hover over to view information

QUESTIONS 6



Rebecca is looking for the information about “Amlodipine Besylate” from 2012 to 2017 and reports from healthcare professional only. Then she decides to look for the reaction hypotension. How many steps does Rebecca need to get her results?

- a. 5
- b. 3
- c. 2
- d. 4

QUESTIONS 6

Rebecca is looking for the information about “Amlodipine Besylate” from 2012 to 2017 and reports from healthcare professional only. Then she decides to look for reaction related to hypotension. How many steps Rebecca need to perform to reach to her results?

- a. 5
- b. 3
- c. 2
- d. 4

Step 1: Select product (Amlodipine Besylate)

Step 2: Select Years (2012 to 2017)

Step 3: Select Reporter Type (healthcare professional)

Step 4: Click on reaction (hypotension)

QUESTIONS 7



Rebecca has applied the age groups 12-17 years and 18-64 in the previous exercise. Now she decides to remove the healthcare professional filter.

What is the best option to remove the healthcare professional filter?

- a. Deselect from "Cases by Reporter Type" page
- b. Unselect Reporter Type from filter section on top
- c. Resetting entire filters
- d. Start a new search

QUESTIONS 8



Rebecca is confused with the information provided in “Case by Sex” as “Not Specified.” While examining the information she asked a question to helpdesk about details of “Not Specified.”

What is the best answer helpdesk can provide?

- a. Sex is reported as unknown
- b. Transgender
- c. Missing gender information
- d. Sex was not reported

QUESTIONS 8



Rebecca is confused with the information provided in “Case by Sex” as “Not Specified.” While examining the information she asked the helpdesk a question about details of “Not Specified.”

What is the best answer the helpdesk can provide?

- a. Sex is reported as unknown
- b. Transgenders
- c. Missing gender information
- d. Sex was not reported

“Not Specified” indicates the patient’s sex was not reported as these reports are voluntary.

REACTION GROUP



Age group filter applied

Total number of cases based on applied filter

Cases by Age Group

FDA Adverse Events Reporting System (FAERS) Public Dashboard

Home Demographics Reaction Group Reaction Listing of Cases Disclaimer Site Feedback Report a Problem FAQ Amlodipine Besyla

AMLODIPINE BESYLATE

Total Cases **5,325**

Serious Cases (including deaths) **4,952**

Death Cases **1,554**

Cases by Age Group

Reaction Groups & Age Group

Reaction Group	Select category	Number of Cases	12-17 Years	18-64 Years
Total Cases		5,325	228	5,097
Psychiatric Disorders		1,895	78	1,817
Injury, Poisoning And Procedural Complications		1,882	168	1,714
Vascular Disorders		1,317	127	1,190
General Disorders And Administration Site Conditions		1,249	74	1,175
Nervous System Disorders		1,126	76	1,050
Cardiac Disorders		1,001	88	913
Respiratory, Thoracic And Mediastinal Disorders		823	39	784
Investigations		800	75	725
Gastrointestinal Disorders		772	55	717
Metabolism And Nutrition Disorders		672	45	627
Renal And Urinary Disorders		643	38	605
Skin And Subcutaneous Tissue Disorders		565	23	542
Musculoskeletal And Connective Tissue Disorders		428	12	408
Infections And Infestations		285	27	258
Immune System Disorders		261	5	256
Hepatobiliary Disorders		186	5	181
Eye Disorders		186	5	181
Blood And Lymphatic System Disorders		180	13	167
Surgical And Medical Procedures		98	8	90

Data as of August 31, 2017

This page displays the number of cases identified for the product of interest by "Reaction Group" and the reported age of the patient. "Reaction Groups" are based on a classification of the side effect (also known as "Reaction" or adverse event or adverse drug reaction), using the MedDRA dictionary of adverse event terms. For example, "Cardiac Disorders" is one of the "Reaction Groups" defined by the MedDRA dictionary as a grouping of several related "Reactions" such as "Cardiac Arrest", and "Cyanosis". A case may contain more than one "Reaction Group". The age has been categorized based on the reported age by the patient. "Not Specified" indicates the patient's age was not reported.

Reaction Groups & Age Group

Reaction Group	12-17 Years	18-64 Years
Psychiatric Disorders	1895	1882
Injury, Poisoning And Procedural Complications	1882	1882
Vascular Disorders	1317	1317
General Disorders And Administration Site Conditions	1249	1249
Nervous System Disorders	1126	1126
Cardiac Disorders	1001	1001
Respiratory, Thoracic And Mediastinal Disorders	823	823
Investigations	800	800
Gastrointestinal Disorders	772	772
Metabolism And Nutrition Disorders	672	672
Renal And Urinary Disorders	643	643
Skin And Subcutaneous Tissue Disorders	565	565
Musculoskeletal And Connective Tissue Disorders	428	428
Infections And Infestations	285	285
Immune System Disorders	261	261
Hepatobiliary Disorders	186	186

Number of Cases

REACTION GROUP



Age group filter applied

Total number of cases based on applied filter

Cases by Sex

FDA Adverse Events Reporting System (FAERS) Public Dashboard

Home Demographics Reaction Group Reaction Listing of Cases Disclaimer Site Feedback Report a Problem FAQ Amlodipine Besylate

AMLODIPINE BESYLATE

Total Cases 5,325

Serious Cases (including deaths) 4,952

Death Cases 1,554

Cases by Sex

Reaction Groups & Sex

Reaction Group	Select category	Number of Cases	Male	Not Specified	Female
Total Cases		5,325	2,660	63	2,602
Psychiatric Disorders		1,895	956	20	919
Injury, Poisoning And Procedural Complications		1,882	894	8	980
Vascular Disorders		1,317	670	3	644
General Disorders And Administration Site Conditions		1,249	583	10	656
Nervous System Disorders		1,126	608	13	505
Cardiac Disorders		1,001	505	4	492
Respiratory, Thoracic And Mediastinal Disorders		823	398	2	423
Investigations		800	390	5	405
Gastrointestinal Disorders		772	326	10	436
Metabolism And Nutrition Disorders		672	307	-	365
Renal And Urinary Disorders		643	362	1	280
Skin And Subcutaneous Tissue Disorders		565	277	10	278
Musculoskeletal And Connective Tissue Disorders		420	182	9	229
Infections And Infestations		285	150	3	132
Immune System Disorders		261	71	16	174
Hepatobiliary Disorders		186	120	2	64
Eye Disorders		186	77	-	109
Blood And Lymphatic System Disorders		180	103	-	77
Surgical And Medical Procedures		98	44	-	54

Reaction Groups & Sex

Reaction Group	Female (Cases)	Male (Cases)	Not Specified (Cases)
Psychiatric Disorders	1,895	1,882	0
Injury, Poisoning And Procedural Complications	1,882	1,882	0
Vascular Disorders	1,317	1,317	0
General Disorders And Administration Site Conditions	1,249	1,249	0
Nervous System Disorders	1,126	1,126	0
Cardiac Disorders	1,001	1,001	0
Respiratory, Thoracic And Mediastinal Disorders	823	823	0
Investigations	800	800	0
Gastrointestinal Disorders	772	772	0
Metabolism And Nutrition Disorders	672	672	0
Renal And Urinary Disorders	643	643	0
Skin And Subcutaneous Tissue Disorders	565	565	0
Musculoskeletal And Connective Tissue Disorders	420	420	0
Infections And Infestations	285	285	0
Immune System Disorders	261	261	0
Hepatobiliary Disorders	186	186	0

Data as of August 31, 2017

This page displays the number of cases identified for the product of interest by "Reaction Group" and the reported age of the patient. "Reaction Groups" are based on a classification of the side effect (also known as "Reaction" or adverse event or adverse drug reaction), using the MedDRA dictionary of adverse event terms. For example, "Cardiac Disorders" is one of the "Reaction Groups" defined by the MedDRA dictionary as a grouping of several related "Reactions" such as "Cardiac Arrest", and "Cyanosis". A case may contain more than one "Reaction Group". The age has been categorized based on the reported age by the patient. "Not Specified" indicates the patient's age was not reported.

REACTION GROUP

Age group filter applied

Additional filter capabilities for Reporter Type

Cases by Reporter Type

Total number of cases based on applied filter

Reaction Group	Number of Cases	Healthcare Professional
Total Cases	5,325	5,325
Psychiatric Disorders	1,895	1,895
Injury, Poisoning And Procedural Complications	1,882	1,882
Vascular Disorders	1,317	1,317
General Disorders And Administration Site Conditions	1,249	1,249
Nervous System Disorders	1,126	1,126
Cardiac Disorders	1,001	1,001
Respiratory, Thoracic And Mediastinal Disorders	823	823
Investigations	800	800
Gastrointestinal Disorders	772	772
Metabolism And Nutrition Disorders	672	672
Renal And Urinary Disorders	643	643
Skin And Subcutaneous Tissue Disorders	565	565
Musculoskeletal And Connective Tissue Disorders	428	428
Infections And Infestations	285	285
Immune System Disorders	261	261
Hepatobiliary Disorders	186	186
Eye Disorders	186	186
Blood And Lymphatic System Disorders	180	180
Surgical And Medical Procedures	98	98

Reaction Groups & Reporter Type

Reaction Group	Number of Cases
Psychiatric Disorders	1,895
Injury, Poisoning And Procedural Complications	1,882
Vascular Disorders	1,317
General Disorders And Administration Site Conditions	1,249
Nervous System Disorders	1,126
Cardiac Disorders	1,001
Respiratory, Thoracic And Mediastinal Disorders	823
Investigations	800
Gastrointestinal Disorders	772
Metabolism And Nutrition Disorders	672
Renal And Urinary Disorders	643
Skin And Subcutaneous Tissue Disorders	565
Musculoskeletal And Connective Tissue Disorders	428
Infections And Infestations	285
Immune System Disorders	261
Hepatobiliary Disorders	186

Data as of August 31, 2017

This page displays the number of cases identified for the product of interest by "Reaction Group" and the reported age of the patient. "Reaction Groups" are based on a classification of the side effect (also known as "Reaction" or adverse event or adverse drug reaction), using the MedDRA dictionary of adverse event terms. For example, "Cardiac Disorders" is one of the "Reaction Groups" defined by the MedDRA dictionary as a grouping of several related "Reactions" such as "Cardiac Arrest", and "Cyanosis". A case may contain more than one "Reaction Group". The age has been categorized based on the reported age by the patient. "Not Specified" indicates the patient's age was not reported.

REACTION GROUP



Age group filter applied

Total number of cases based on applied filter

Cases by Reporter Region

FDA Adverse Events Reporting System (FAERS) Public Dashboard

FDA U.S. FOOD & DRUG ADMINISTRATION

Home Demographics Reaction Group Reaction Listing of Cases Disclaimer Site Feedback Report a Problem FAQ Amlodipine Besylate

AMLODIPINE BESYLATE

Total Cases 5,325

Serious Cases (including deaths) 4,952

Death Cases 1,554

Cases by Reporter Region

Reaction Groups & Reporter Region

Reaction Group	Number of Cases	Domestic	Foreign	Not Specified
Total Cases	5,325	2,682	2,626	17
Psychiatric Disorders	1,895	1,405	486	4
Injury, Poisoning And Procedural Complications	1,882	1,112	769	1
Vascular Disorders	1,317	589	726	2
General Disorders And Administration Site Conditions	1,249	527	713	9
Nervous System Disorders	1,126	381	740	5
Cardiac Disorders	1,001	585	414	2
Respiratory, Thoracic And Mediastinal Disorders	823	359	460	4
Investigations	800	296	497	7
Gastrointestinal Disorders	772	224	544	4
Metabolism And Nutrition Disorders	672	299	372	1
Renal And Urinary Disorders	643	299	342	2
Skin And Subcutaneous Tissue Disorders	565	189	371	5
Musculoskeletal And Connective Tissue Disorders	420	130	287	3
Infections And Infestations	285	102	183	-
Immune System Disorders	261	205	56	-
Hepatobiliary Disorders	186	34	152	-
Eye Disorders	186	35	148	3
Blood And Lymphatic System Disorders	180	27	153	-
Surgical And Medical Procedures	98	47	49	2

Reaction Groups & Reporter Region

Reaction Group	Domestic	Foreign	Not Specified
Psychiatric Disorders	1,405	486	4
Injury, Poisoning And Procedural Complications	1,112	769	1
Vascular Disorders	589	726	2
General Disorders And Administration Site Conditions	527	713	9
Nervous System Disorders	381	740	5
Cardiac Disorders	585	414	2
Respiratory, Thoracic And Mediastinal Disorders	359	460	4
Investigations	296	497	7
Gastrointestinal Disorders	224	544	4
Metabolism And Nutrition Disorders	299	372	1
Renal And Urinary Disorders	299	342	2
Skin And Subcutaneous Tissue Disorders	189	371	5
Musculoskeletal And Connective Tissue Disorders	130	287	3
Infections And Infestations	102	183	-
Immune System Disorders	205	56	-
Hepatobiliary Disorders	34	152	-
Eye Disorders	35	148	3
Blood And Lymphatic System Disorders	27	153	-
Surgical And Medical Procedures	47	49	2

Data as of August 31, 2017

This page displays the number of cases identified for the product of interest by "Reaction Group" and the reported age of the patient. "Reaction Groups" are based on a classification of the side effect (also known as "Reaction" or adverse event or adverse drug reaction), using the MedDRA dictionary of adverse event terms. For example, "Cardiac Disorders" is one of the "Reaction Groups" defined by the MedDRA dictionary as a grouping of several related "Reactions" such as "Cardiac Arrest", and "Cyanosis". A case may contain more than one "Reaction Group". The age has been categorized based on the reported age by the patient. "Not Specified" indicates the patient's age was not reported.

QUESTIONS 9



Rebecca has extended her search and now she wants to view the information for only domestic cases and under nervous system disorders.

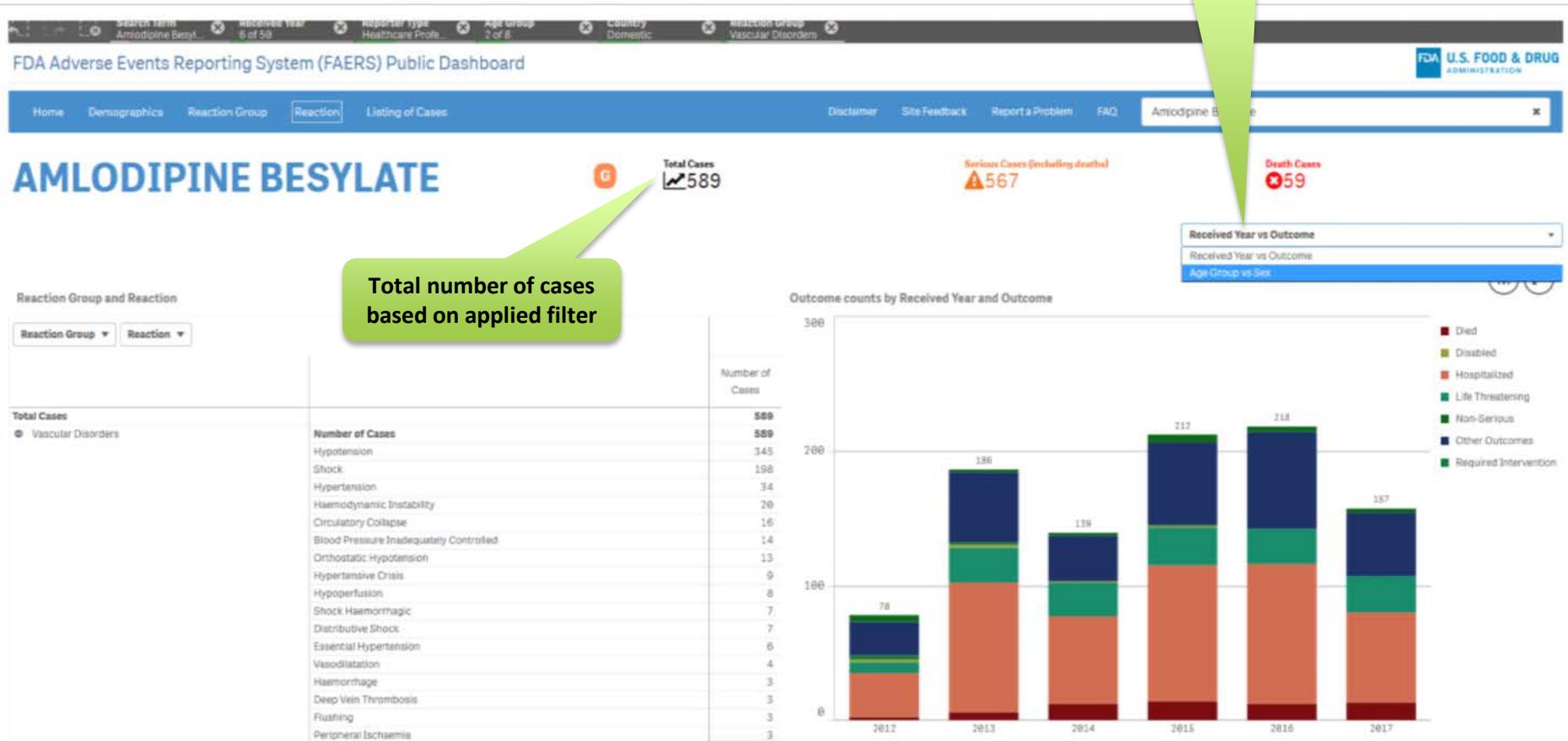
Which selections steps are the best to get quickly to results?

- a. Click on graph view and select “Nervous System Disorders” and “Domestic”
- b. Click on table view and select “Nervous System Disorders” and “Domestic”
- c. a or b

REACTION



Cases by Reaction Year vs Outcomes



REACTION



Cases by Age Group vs Sex

QUESTIONS 10



Rebecca was reviewing the chart “Reaction Year vs Outcome”. She noticed that cases have one or more outcomes. Is this correct that one case can have one or more reported outcomes?

- a. Yes
- b. No

QUESTIONS 11



Rebecca has found 3 cases on “Deep Vein Thrombosis” from product search “Amlodipine Besylate.” Does she has enough information to determine that “Amlodipine Besylate” cause the reaction “Deep Vein Thrombosis?” Choose the best answer.

- a. “Amlodipine Besylate” caused serious “Deep Vein Thrombosis” reaction
- b. “Amlodipine Besylate” did not cause serious “Deep Vein Thrombosis” reaction
- c. “Amlodipine Besylate” may have caused “Deep Vein Thrombosis” reaction
- d. Not enough information to determine the causal relation

QUESTIONS 11



Rebecca has found 3 cases on “Deep Vein Thrombosis” from product search “Amlodipine Besylate.” Does she has enough information to determine that “Amlodipine Besylate” cause the reaction “Deep Vein Thrombosis?” Choose the best answer.

- a. “Amlodipine Besylate” caused serious “Deep Vein Thrombosis” reaction
- b. “Amlodipine Besylate” did not cause serious “Deep Vein Thrombosis” reaction
- c. “Amlodipine Besylate” may have caused “Deep Vein Thrombosis” reaction
- d. Not enough information to determine the causal relation

One or more of these outcomes or reported reactions in a report does not necessarily mean that the suspect product of interest was the cause of the reported outcomes or reactions. Also reported narrative is not available in the public data.

LINE LISTING



Total number of cases based on applied filter

Sort Option

FDA Adverse Events Reporting System (FAERS) Public Dashboard

Home Demographics Reaction Group Reaction Listing of Cases Disclaimer Site Feedback Report a Problem FAQ

AMLODIPINE BESYLATE

Total Cases 589

Serious Cases (including deaths) 567

Death Cases 59

Sort Option

Case IDs

Search within each displayed column

Additional columns available to view

Case ID	Suspect Product Names	Suspect Product Active Ingredients	Reason for Use	Reactions	Serious	Outcomes	Sex	Event Date	Latest FDA Recel...
9371793		Amlodipine Besylate	Intentional Overdose	Metabolic Acidosis;Hypotension;SI... Tachycardia;Overdose;A...	Serious	Hospitalized	Female	01-APR-2013	25-JUN-2013
8336357	Vagra	Sildenafil Citrate;Amlodipine Besylate	Erectile Dysfunction;Hypertension	Drug Ineffective;Chest Pain;Wrong Technique In Product Usage	Serious	Other Outcomes	Male	01-JAN-2011	17-FEB-2012
18528890	Amlodipine	Amlodipine Besylate;Basiliximab;Tacrolimus	Hypertension;Immunosuppression;Used For Unknown Indication;Renal Transplant	Respiratory Rate Decreased;Bilirubin Conjugated	Serious	Hospitalized;Other Outcomes	Male	01-JUN-2014	28-OCT-2014
8492696	Bystolic;Norvasc	Nebivolol Hydrochloride;Amlodipine Besylate	Cardiac Disease;Heart Rate Irregular;Hypertension;Seizure	Renal Failure;Palpitations;Abd. Distension;Oedema	Serious	Other Outcomes	Female	01-MAY-2011	06-APR-2012
8515587	Norvasc;Humira	Adalimumab;Amlodipine Besylate;Lisinopril	Gastroesophageal Reflux Disease;Product Used For Unknown Indication;Psoriatic Arthritis	Headache;Oedema;Peripheral Palpitations;Potassium	Non-Serious	Non-Serious	Female	01-OCT-2011	18-MAY-2012
18212221	Vasotec;Lyrica;Enbrel;Ampyra;Ryth...	Amlodipine Besylate;Cyclobenzaprine Hydrochloride;Leflunomide;Piperacillin Sodium;Tazobactam	Arhythmia;Atrial Fibrillation;Blood Pressure Measurement;Fibromyalgia;Impaired Mouth Function	Retching;Alopecia;Judgment Impaired;Mouth Ulceration;Fatigue;Colic	Serious	Hospitalized;Other Outcomes	Female	02-FEB-2007	07-JUL-2014
11538666	Macrodantin;Cipro;Wellbutrin;Macr...	Nitrofurantoin;Nitrofurantoin Monohydrate;Lisinopril;Bupropion Hydrochloride;Ciprofloxacin	Product Used For Unknown Indication	Loss Of Consciousness;Hypotension;Numbness;Drug	Serious	Other Outcomes	Female	02-JUN-2015	16-OCT-2015
8256880	Amlodipine;Herceptin	Trastuzumab;Amlodipine Besylate;Epothilone D;Metoprolol Succinate;Carboplatin;Lorazepam	Breast Cancer;Product Used For Unknown Indication	Confusion;Dehydration;Dizziness;Hypotension;Incontinence;Urinary Tract Infection;Urinary Tract Inflammation;Urinary Tract Obstruction;Urinary Tract Spasm;Urinary Tract Tumor;Urinary Tract Ulcer;Urinary Tract Wall Thickening;Urinary Tract Wound愈合	Serious	Hospitalized	Female	02-SEP-2005	31-MAR-2012
8648567	Levamlodipine And Hydrochlorothiazide;Amlodipine;Co...	Carvediol;Amlodipine Besylate;Clonidine;Hydrochlorothiazide;Potassium;Investigational Product	Hypertension;Non-Small Cell Lung Cancer	Anorexia;Hypotension;A... Respiratory Distress Syndrome;Urinary Tract Kidney...	Serious	Died;Other Outcomes;Disabled	Male	02-SEP-2012	02-SEP-2014
8647273	Coreg	Carvediol;Clonidine;Hydrochlorothiazide;Potassium;Amlodipine Besylate	Hypertension	Sepsis;Respiratory Distress Syndrome;Urinary Tract Inflammation	Serious	Disabled;Other Outcomes;Died;H... Threatening	Male	02-SEP-2012	04-FEB-2013
18574165	Lioresal;Amlodipine	Amlodipine Besylate;Baclofen	Muscle Spasticity;Product Used For...	Incorrect Rosiglitazone Dosage	Serious	Life	Male	03-OCT-2014	18-NOV-2014

LINE LISTING



FDA Adverse Events Reporting System (FAERS) Public Dashboard

Total number of cases based on applied filter

Sort Option

Case IDs

Search within each displayed column

Additional columns available to view

AMLODIPINE BESYLATE

Case ID	Suspect Product Names	Suspect Product Active Ingredients	Reason for Use	Reactions	Serious	Outcomes	Sex	Event Date	Latest FDA Recel...
9371793	-	Amiodipine Besylate	Intentional Overdose	Metabolic Acidosis;Hypotension;SI-Tachycardia;Overdose,A...	Serious	Hospitalized	Female	01-APR-2013	25-JUN-2013
8336357	Vagra	Sildenafil Citrate;Amiodipine Besylate	Erectile Dysfunction;Hypertension	Drug Ineffective;Chest Pain;Wrong Technique In Product Usage	Serious	Other Outcomes	Male	01-JAN-2011	17-FEB-2012
18528890	Amiodipine	Amiodipine Besylate;Basiliximab;Tacrolimus	Hypertension;Immunosuppression;Used For Unknown Indication;Renal Transplant	Respiratory Rate Decreased;Bilirubin Conjugated	Serious	Hospitalized;Other Outcomes	Male	01-JUN-2014	
8482696	Bystolic;Norvasc	Nebivolol Hydrochloride;Amiodipine Besylate	Cardiac Disorders;Heart Rate Irregular;Hypertension;Seizure	Renal Failure;Palpitations;Abd. Distension;Oedema	Serious	Other Outcomes	Female	01-MAY-2011	
8515583	Norvasc;Humira	Adalimumab;Amiodipine Besylate;Lisinopril	Gastroesophageal Reflux Disease;Product Used For Unknown Indication;Peptic Arthritis	Headache;Oedema Peripheral;Palpitations;Potassium	Non-Serious	Non-Serious	Female	01-OCT-2011	
19212221	Vasotec;Lyrica;Enbrel;Ampyra;Ryth...	Amiodipine Besylate;Cyclobenzaprine Hydrochloride;Lefunomide;Piperacillin Sodium;Tazobactam	Arthritis;Atrial Fibrillation;Blood Pressure Measurement;Fibromyalgia;Flatulence	Retching;Alopecia;Jugular Impaired;Mouth Ulceration;Fatigue;Colic	Serious	Hospitalized;Other Outcomes	Female	02-FEB-2007	
11536606	Macrodantin;Cipro;Wellbutrin;Macr...	Nitrofurantoin;Nitrofurantoin Monohydrate;Lisinopril;Bupropion Hydrochloride;Ciprofloxacin	Product Used For Unknown Indication	Loss Of Consciousness;Hypotension	Serious	Other Outcomes	Female	02-JUN-2015	
8256800	Amiodipine;Herceptin	Tрастузумаб;Amiodipine Besylate;Eptololone D;Metoprolol Succinate;Carboplatin;Lorazepam	Breast Cancer;Product Used For Unknown Indication	Dehydration;Diarrhoea	Serious	Hospitalized	Female	02-SEP-2005	31-JUL-2012
6846567	Lisinopril Hydrochlorothiazide;Amiodipine;Co...	Carvedilol;Amiodipine Besylate;Clonidine;Hydrochlorothiazide;Potassium;Investigational Product	Hypertension;Non-Small Cell Lung Cancer	Anaemia;Hypotension;A... Respiratory distress Syndrome;Kidney...	Serious	Died;Other Outcomes;Disable...	Male	02-SEP-2012	06-SEP-2014
8847273	Coreg	Carvedilol;Clonidine;Hydrochlorothiazide;Potassium;Amiodipine Besylate	Hypertension	Sepsis;Admission;Respiratory Distress Syndrome;Hypotension	Serious	Disabled;Other Outcomes;Died;H... Threatening	Male	02-SEP-2012	15-FEB-2013
18574105	Lioresal;Amiodipine	Amiodipine Besylate;Baclofen	Muscle Spasticity;Product Used For...	Incorrect Route	Serious	Life	Male	03-OCT-2014	18-NOV-2014

LINE LISTING



Search within each displayed column

FDA Adverse Events Reporting System (FAERS) Public Dashboard

FDA U.S. FOOD & DRUG ADMINISTRATION

AMLODIPINE BESYLATE

Total Cases **589**

Serious Cases (including deaths) **567**

Death Cases **59**

Case ID	Suspect Product Names	Suspect Product Active Ingredients	Reason for Use	Actions	Serious	Outcomes	Sex	Event Date	Latest FDA Recel...
9371793	-	Amlodipine Besylate	Intentional Overdose	X ✓	Serious	Hospitalized	Female	01-APR-2013	25-JUN-2013
8336357	Viagra	Sildenafil Citrate;Amlodipine Besylate	Erectile Dysfunction	X ✓	Chest Pain;Serious	Other Outcomes	Male	01-JAN-2011	17-FEB-2012
18528890	Amlodipine	Amlodipine Besylate;Basiliximab;Tacrolimus	Hypertension;Used For Unsuccessful Transplant	X ✓	Adenocarcinoma Of Colon;Hypertension	Hospitalized;Other Outcomes	Male	01-JUN-2014	29-OCT-2014
8492696	Bystolic;Norvasc	Nitivoltol Hydrochloride;Amlodipine Besylate	Cardiac Disease;Irregular Heartbeat	X ✓	Angina Pectoris;Anticoagulant Therapy	Other Outcomes	Female	01-MAY-2011	06-APR-2012
8515582	Norvasc;Humira	Adalimumab;Amlodipine Besylate;Lisinopril	Gastroesophageal Reflux Disease;Product Indication;Poor Response	X ✓	Angina Pectoris;Coronary Artery Disease	Non-Serious	Female	01-OCT-2011	18-MAY-2012
10212221	Valetac;Lyrica;Entrel;Amyoya;Rhyth...	Amlodipine Besylate;Cyclobenzaprine Hydrochloride;Leflunomide;Piperacillin Sodium;Tazobactam	Arthritis;Atrial Fibrillation;Blood Pressure Measurement;Fibromyalgia;Fluid	X ✓	Antiretroviral Therapy;Product Used For	Severe;Judged	Female	02-FEB-2007	07-JUL-2014
11538666	Macrodantin;Cipro;Wellbutrin;Macr...	Nitrofurantoin;Nitrofurantoin Monohydrate;Lisinopril;Supropion Hydrochloride;Corofloxacin	Product Used For Unknown Indication	X ✓	Loss Of Consciousness;Hypotension;Pruritic;Drug	Other Outcomes	Female	02-JUN-2015	16-OCT-2015
8256880	Amlodipine;Herceptin	Trastuzumab;Amlodipine Besylate;Epothilone D;Metoprolol Succinate;Carboxipran;Lorazepam	Breast Cancer;Product Used For Unknown Indication	X ✓	Vision Blurred;Dehydration;Disorientation	Hospitalized	Female	02-SEP-2005	31-MAY-2012
8846567	Losartan And Hydrochlorothiazide;Amlodipine;Co...	Carvedilol;Amlodipine Besylate;Clonidine;Hydrochlorothiazide;Potassium;Investigational Product	Hypertension;Non-Small Cell Lung Cancer	X ✓	Anaemia;Hypotension;Acute Respiratory Distress Syndrome;Acute Kidney Injury	Died;Other Outcomes;Disable...	Male	02-SEP-2012	04-SEP-2014
8847373	Coreg	Carvedilol;Clonidine;Hydrochlorothiazide;Potassium;Amlodipine Besylate	Hypertension	X ✓	Sepsis;Acute Respiratory Distress Syndrome;Hypoxia;Hypotension	Disabled;Other Outcomes;Died;Highly Threatening	Male	02-SEP-2012	15-FEB-2013
18574105	Lioresal;Amlodipine	Amlodipine Besylate;Baclofen	Muscle Spasticity;Product Used For	X ✓	Incorrect Route Of Drug	Life	Male	03-OCT-2014	18-NOV-2014

Data as of August 31, 2013

QUESTIONS 12



Rebecca got results of 589 total cases for “Amlodipine Besylate.” She finds the line listing is very useful and is curious to see all available data columns.

Is it possible to view all the columns at one time?

- a. Yes
- b. No

QUESTIONS 12



Rebecca got results of 589 cases for “Amlodipine Besylate” based on the filter applied. She finds the line listing is very useful and curious to see all available data columns. Is it possible to view all column at one time?

- a. Yes
- b. No

The export option is not yet available to view all data columns. The only way is to select from the column library to include in the screen to view.

QUESTIONS 13

Rebecca wants detailed narratives to perform further analysis on these reports. The narrative data column is not available to public. What is the best method to get to the full details of all ICSRs?

- a. Make a FOIA request with all 589 case
- b. Send a Request to DrugInfo@FDA.HHS.GOV
- c. Send a Request to FDA Helpdesk
- d. None of the above

CONCLUSION



- FAERS dashboard gives the public and industry a more user friendly platform for accessing FAERS reports
- FAERS dashboard makes adverse event data more accessible and transparent.
- Existence of a report does not establish causation
- Rates of occurrence cannot be established with reports

