U.S. FOOD & DRUG ADMINISTRATION

"An update to the FDA Adverse Event Reporting System (FAERS) Public Dashboard"

Date: October 9th, 2018

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DISCLAIMER

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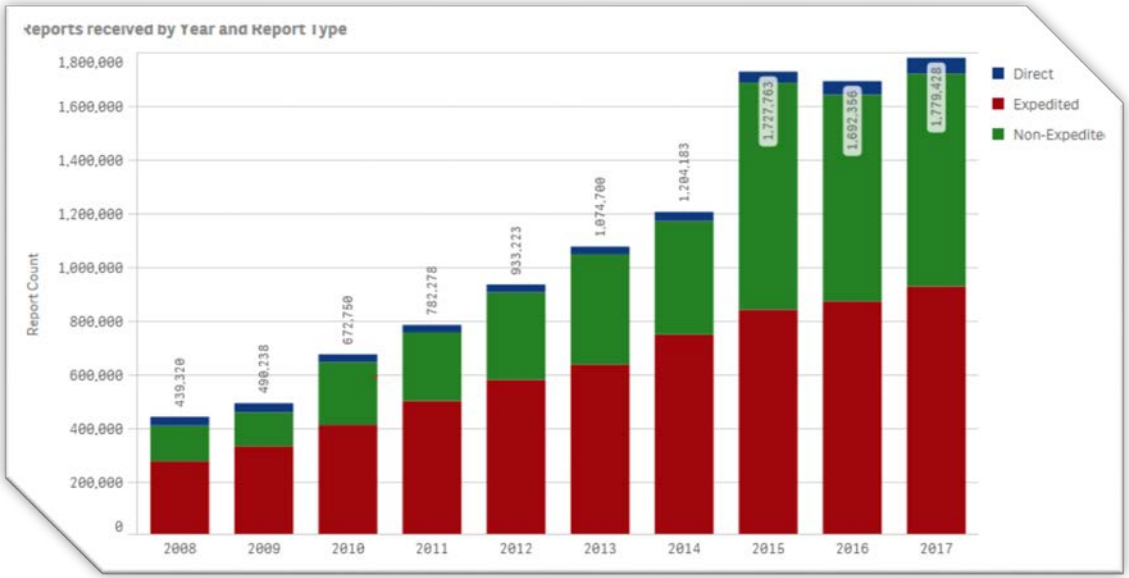
LEARNING OBJECTIVES

- ❑ Describe the FAERS public database and summarize the recent updates.
- ❑ Demonstrate how to use the FAERS public dashboard to view information on 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 **fifteen (15) million reports** since 1969 to June 2018. 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:

JSON File(s)

openFDA

Open FDA

FAERS Quarterly Data Extracts (QDE)

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.

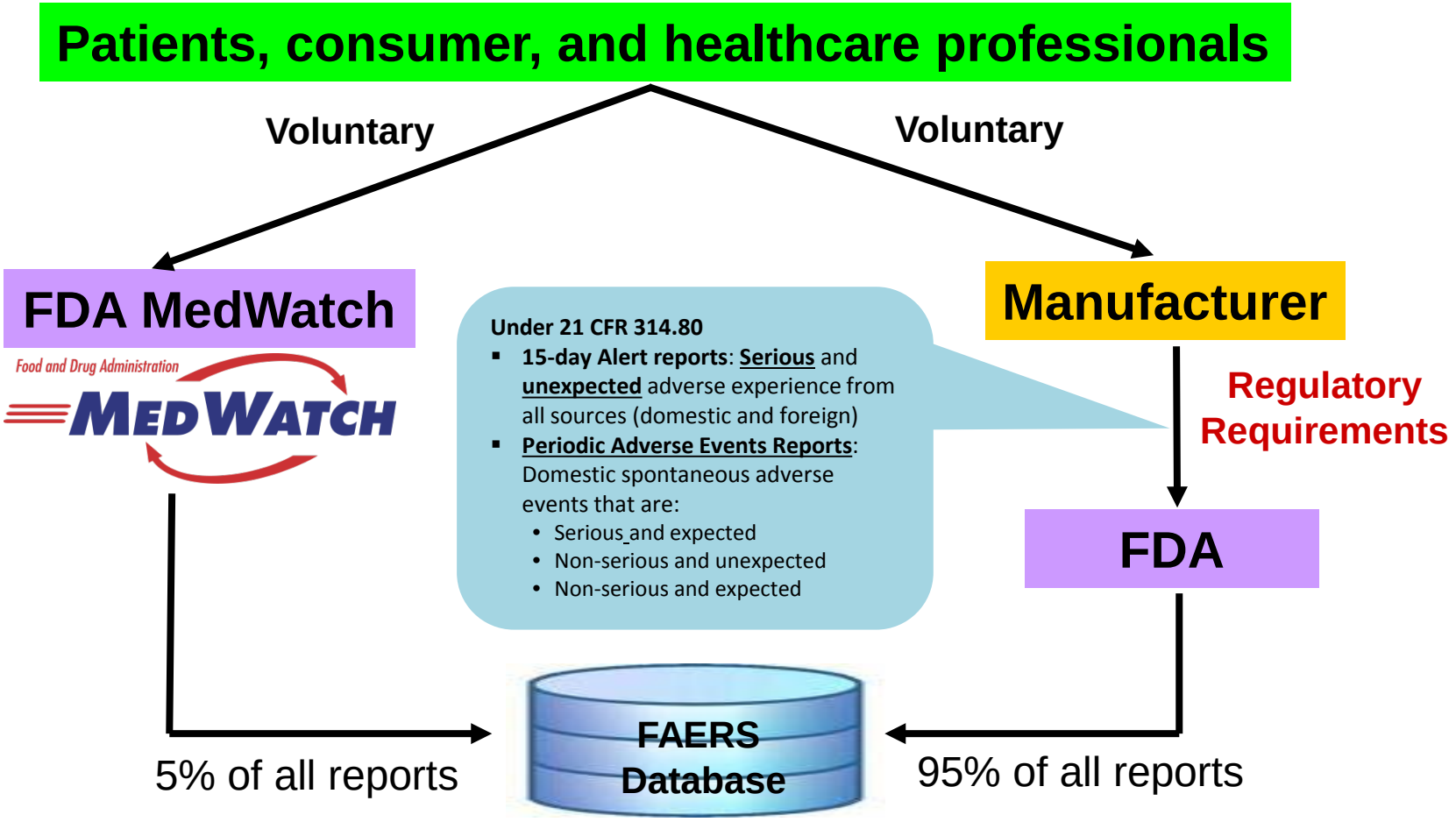
SPONTANEOUS REPORTS

- 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

- 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



FAERS STRENGTHS

- Includes all U.S. marketed products
- Includes all uses
- Includes broad patient populations:
  - elderly, children, pregnant women, co-morbidities
- 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

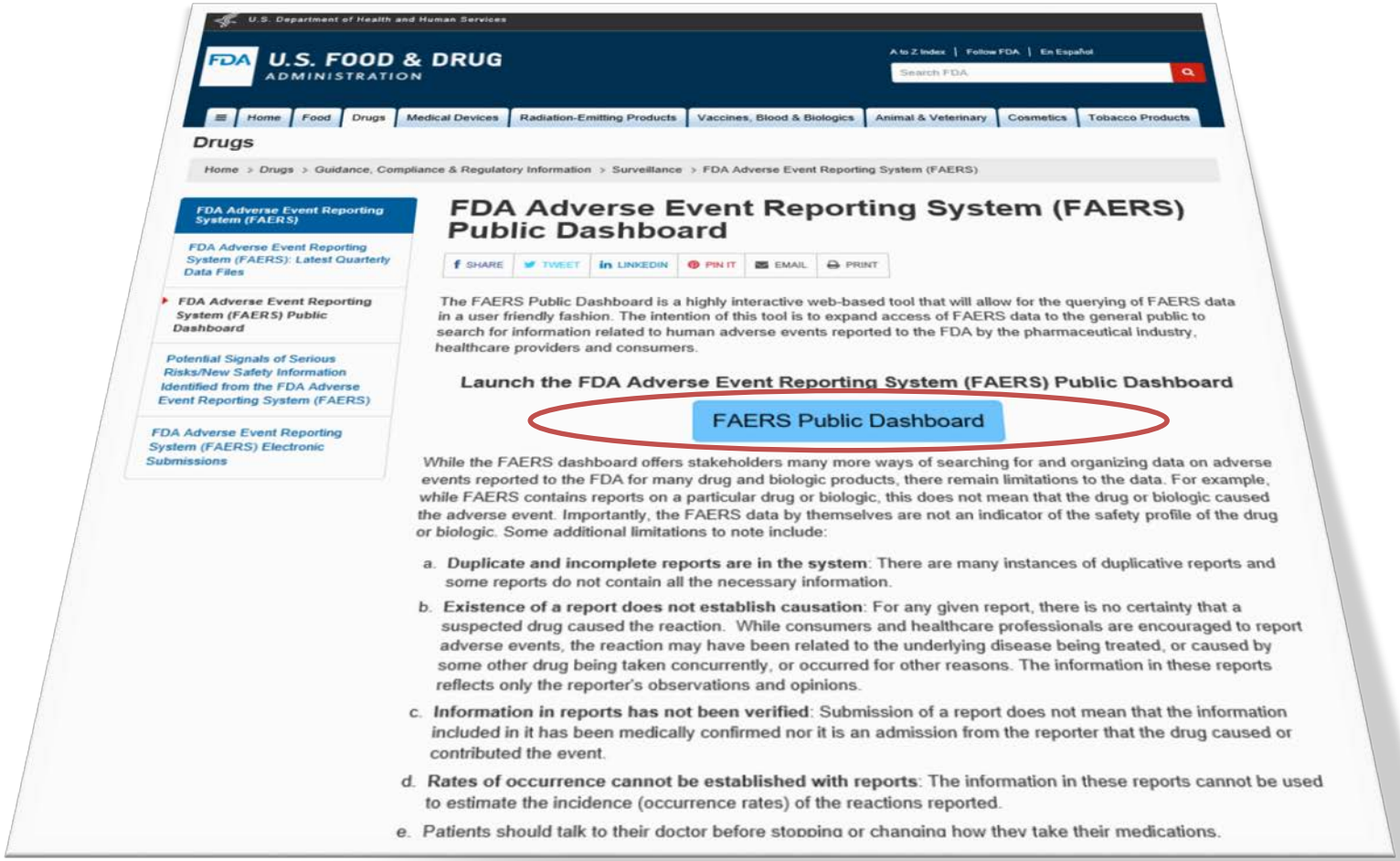
FAERS IS LESS USEFUL FOR

- 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

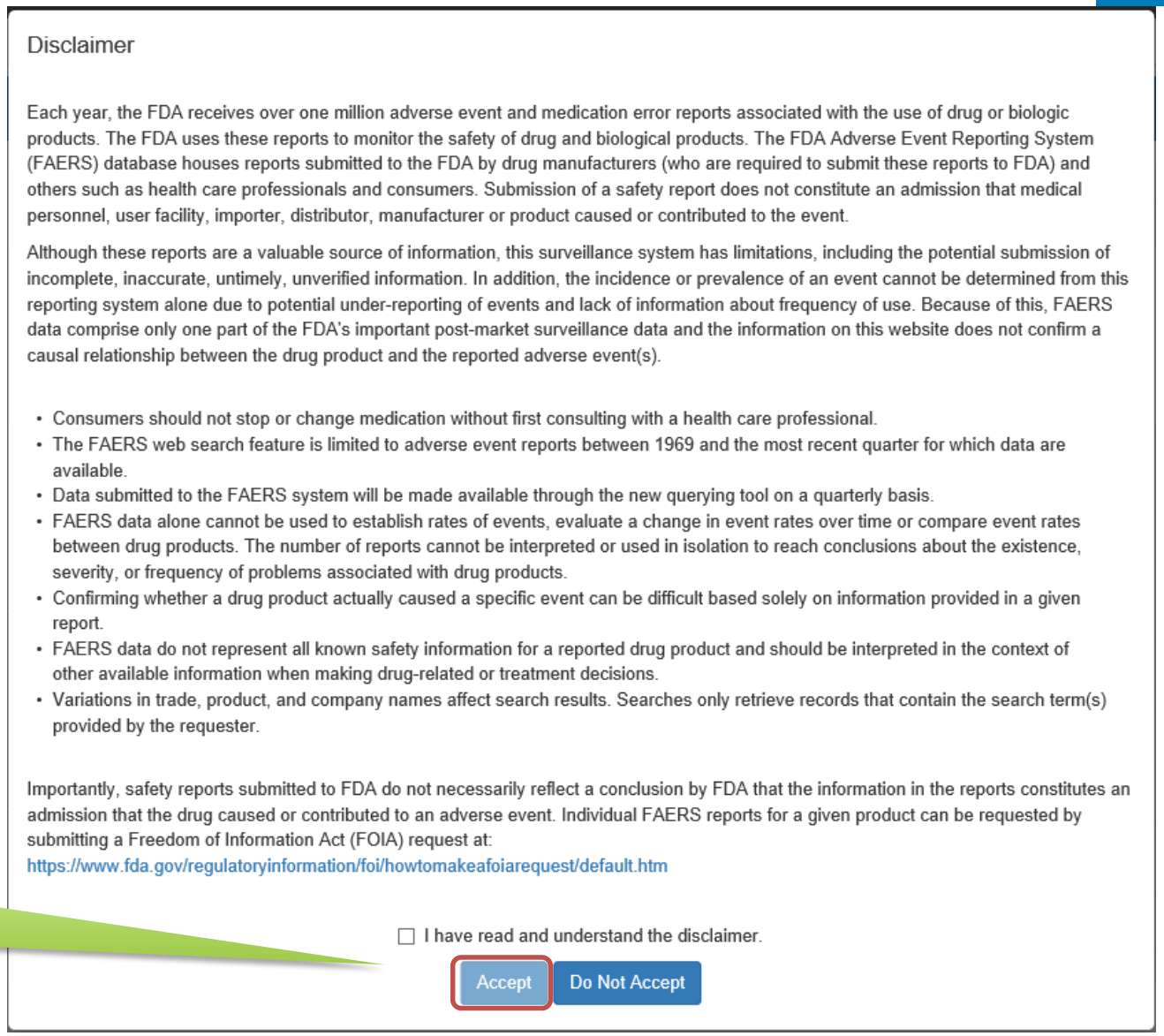
FAERS PUBLIC DASHBOARD

LAUNCH FAERS PUBLIC DASHBOARD

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



DISCLAIMER

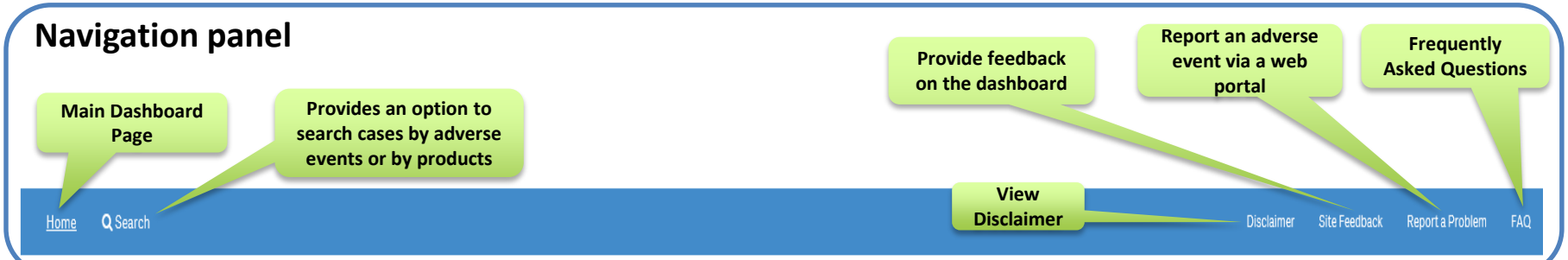


Click on the check box to acknowledge and click on "Accept" to view information on the dashboard

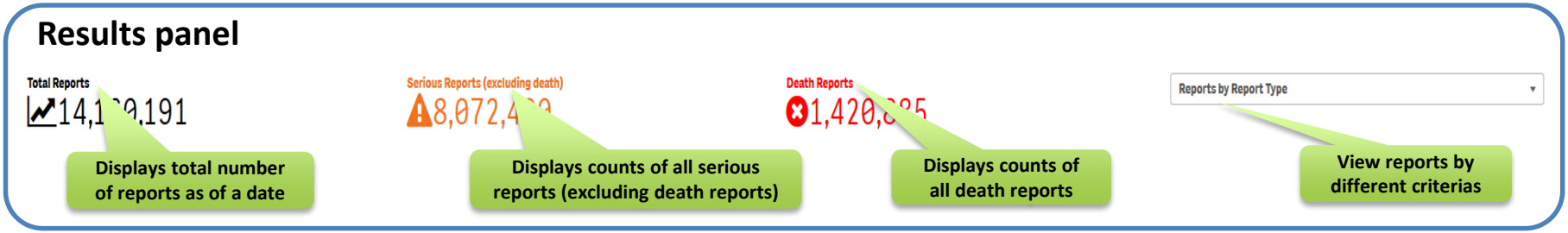
KEY PARTS OF DASHBOARD

Filter panel

Navigation panel



Results panel



KEY PARTS OF DASHBOARD

Data panel

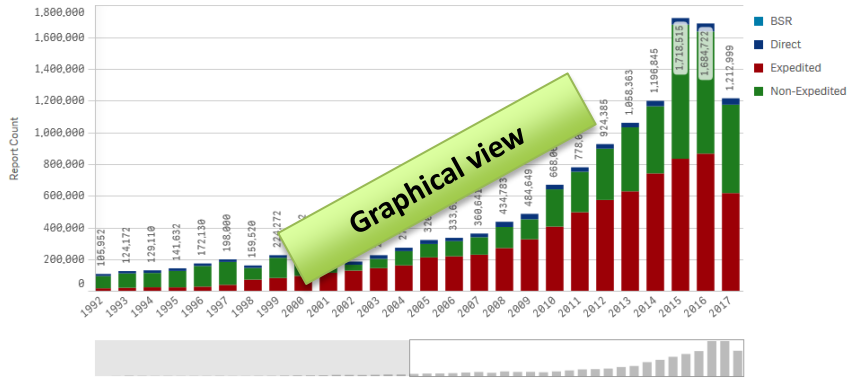
Reports received by Year and Report Type

Year ▾ | Category ▾

	Total Reports	Expedited	Non-Expedited	Direct	BSR
Total Reports	**14,160,191**	**7,437,939**		**739,781**	**873**
2017	**1,212,999**	615,558		40,383	-
2016	**1,684,722**	864,309		50,879	-
2015	**1,718,515**	831	45,052	41,539	-
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**		255,058	27,995	-
2010	**66**	404,586	234,578	28,902	-
2009	**484**	324,421	126,138	34,090	-
2008	**434,7**	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	**224,244**	142,759	58,601	22,879	14

Tabular view

Reports received by Year and Report Type



Graphical view

Page help panel

Describes the details of data displayed on the page

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

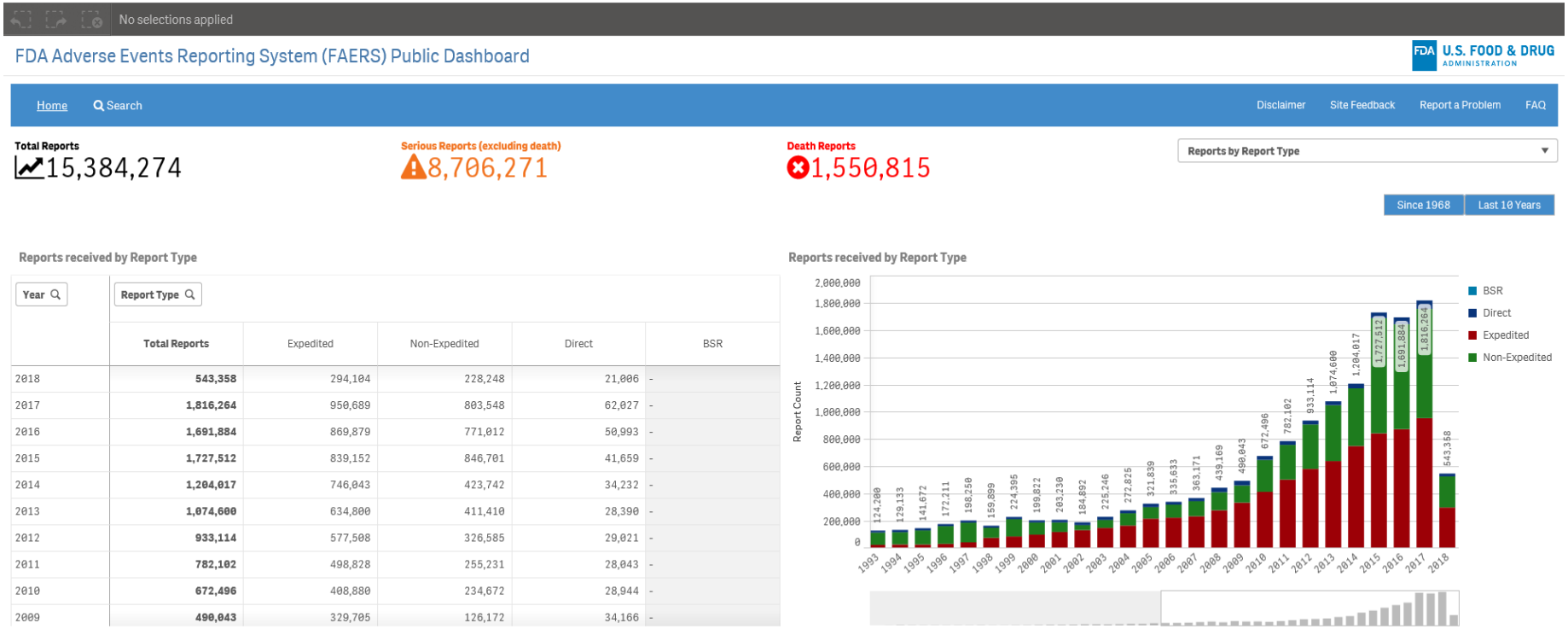
  ii. Non-expedited reports that do not meet the criteria for expedited reports, including cases that are reported as Serious and expected, Non-serious and unexpected and Non-serious and expected.

MAIN DASHBOARD 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



Year	Total Reports	Expedited	Non-Expedited	Direct	BSR
2018	**543,358**	294,104	228,248	21,006	-
2017	**1,816,264**	950,689	803,548	62,027	-
2016	**1,691,884**	869,879	771,012	50,993	-
2015	**1,727,512**	839,152	846,701	41,659	-
2014	**1,204,017**	746,043	423,742	34,232	-
2013	**1,074,600**	634,800	411,410	28,390	-
2012	**933,114**	577,508	326,585	29,021	-
2011	**782,102**	498,828	255,231	28,043	-
2010	**672,496**	408,880	234,672	28,944	-
2009	**490,043**	329,705	126,172	34,166	-

Data as of March 31, 2018

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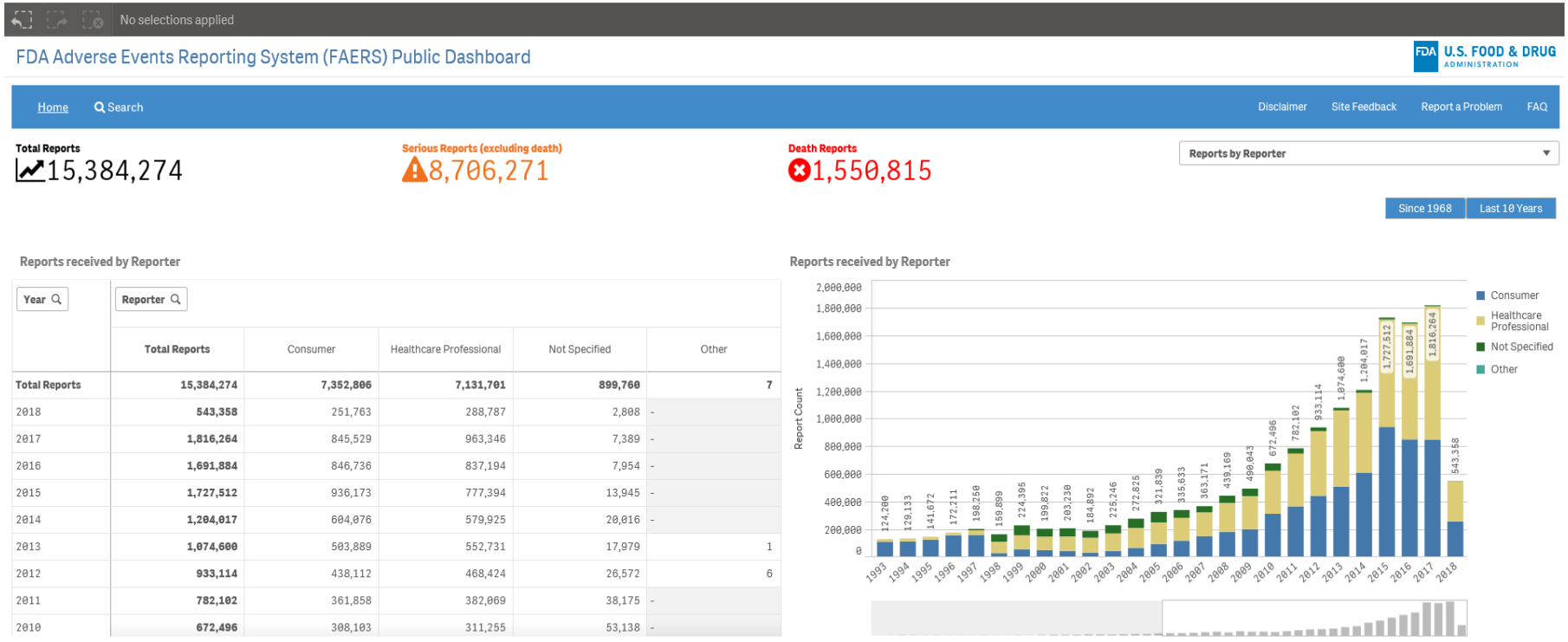
  - ii. Non-expedited reports that do not meet the criteria for expedited reports, including cases that are reported as Serious and expected, Non-serious and unexpected and Non-serious and expected.
- BSR Reports are 15-day Biologic Safety Reports which were submitted to FDA as a separate report type until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

MAIN DASHBOARD
REPORTS BY REPORTER

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



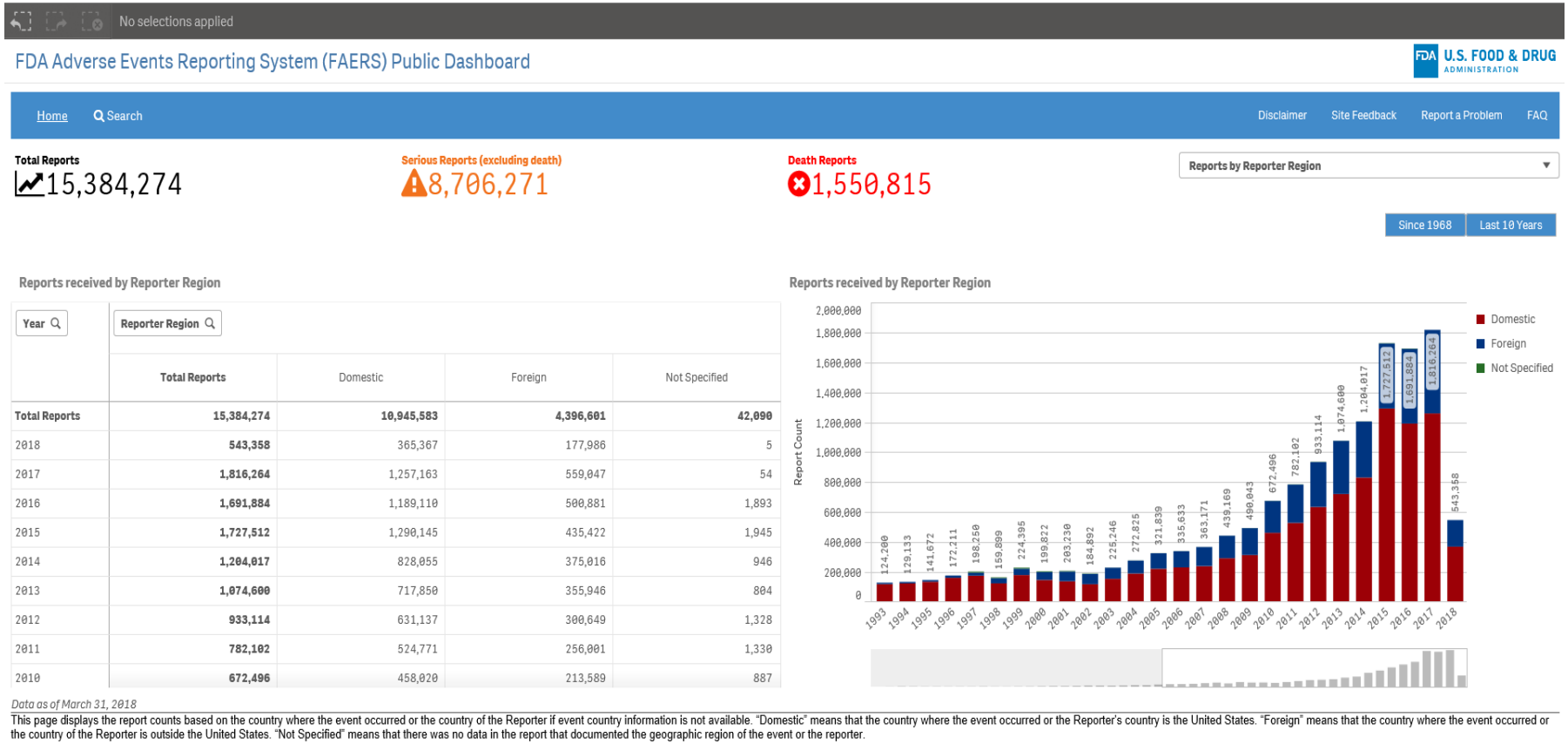
Data as of March 31, 2018

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.

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.



Year	Reporter Region	Total Reports	Domestic	Foreign	Not Specified
Total Reports		15,384,274	10,945,583	4,396,601	42,090
2018		543,358	365,367	177,986	5
2017		1,816,264	1,257,163	559,047	54
2016		1,691,884	1,189,110	500,881	1,893
2015		1,727,512	1,290,145	435,422	1,945
2014		1,204,017	828,055	375,016	946
2013		1,074,600	717,850	355,946	804
2012		933,114	631,137	300,649	1,328
2011		782,102	524,771	256,001	1,330
2010		672,496	458,020	213,589	887

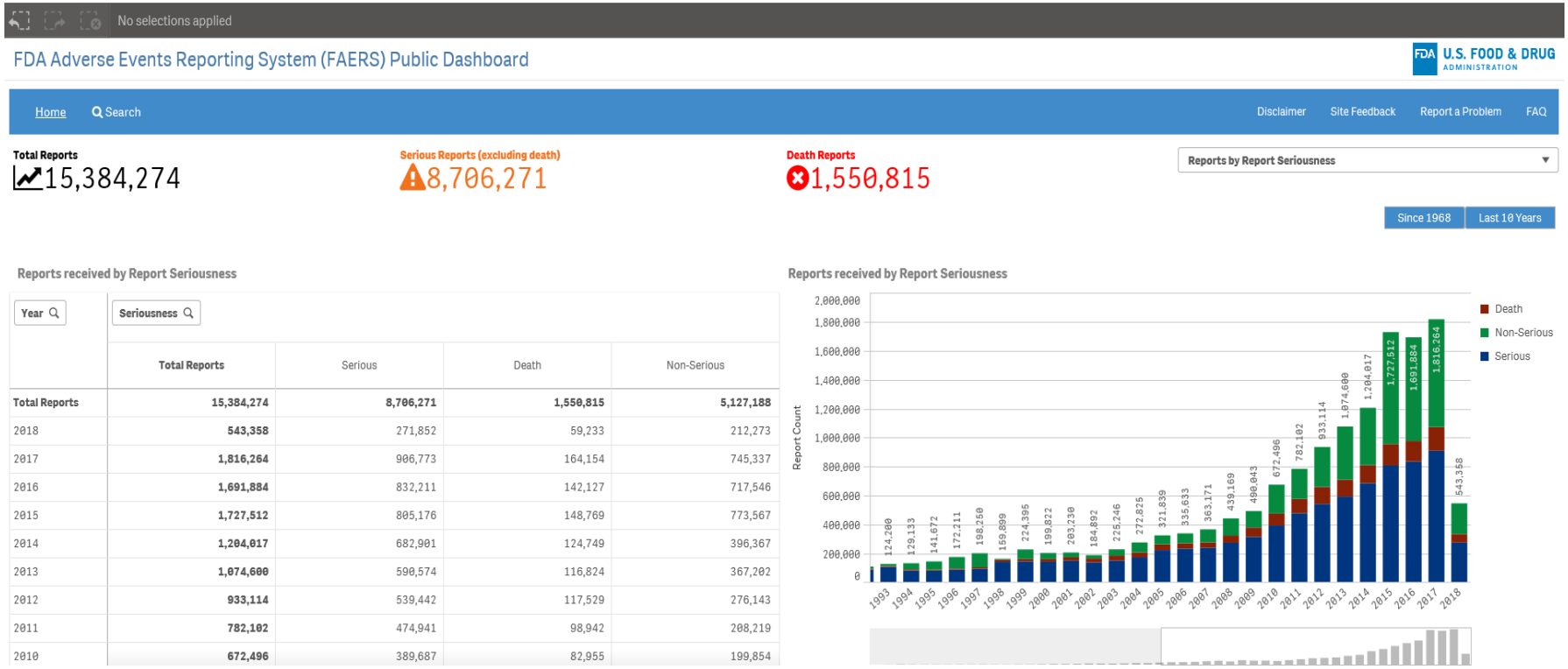
Data as of March 31, 2018

This page displays the report counts based on the country where the event occurred or the country of the Reporter if event country information is not available. "Domestic" means that the country where the event occurred or the Reporter's country is the United States. "Foreign" means that the country where the event occurred or the country of the Reporter is outside the United States. "Not Specified" means that there was no data in the report that documented the geographic region of the event or the reporter.

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)



Data as of March 31, 2018

This page displays the report counts by the outcome of the patient as defined in U.S. reporting regulations (21 CFR 310.305, 314.80, 314.98, 600.80) and Forms FDA 3500 and 3500A. "Serious" indicates that one or more of the following outcomes, excluding death, were documented in the report: hospitalization, life-threatening, disability, congenital anomaly, required intervention, and/or other serious outcome. "Death" indicates that the outcome was documented as Death. "Non-Serious" is used for outcomes which were not documented as Serious or Death.

SEARCH BY PRODUCTS OR REACTION TERMS

SEARCH BY PRODUCTS

Click here to search

No selections applied

FDA Adverse Events Reporting System (FAERS) Public Dashboard

U.S. FOOD & DRUG ADMINISTRATION

Home | Search | Disclaimer | Site Feedback | Report a Problem | FAQ

Total Reports 15,384,274

Serious Reports (excluding death) 8,706,271

Death Reports 1,550,815

Reports by Report Type

Since 1968 | Last 10 Years

Reports received by Report Type

Year | Report Type

	Total Reports	Expedited	Non-Expedited	Direct	BSR
2018	**543,358**	294,104	228,248	21,006	-
2017	**1,816,264**	950,689	803,548	62,027	-
2016	**1,691,884**	869,879	771,012	50,993	-
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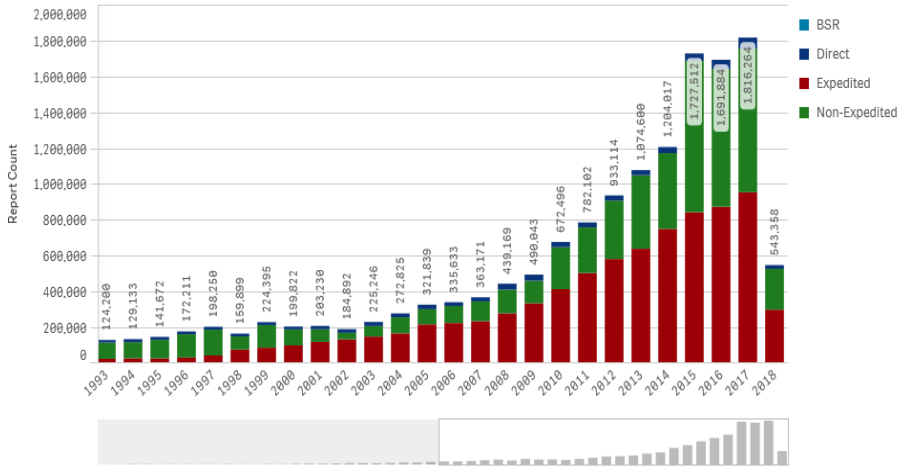
Reports received by Report Type



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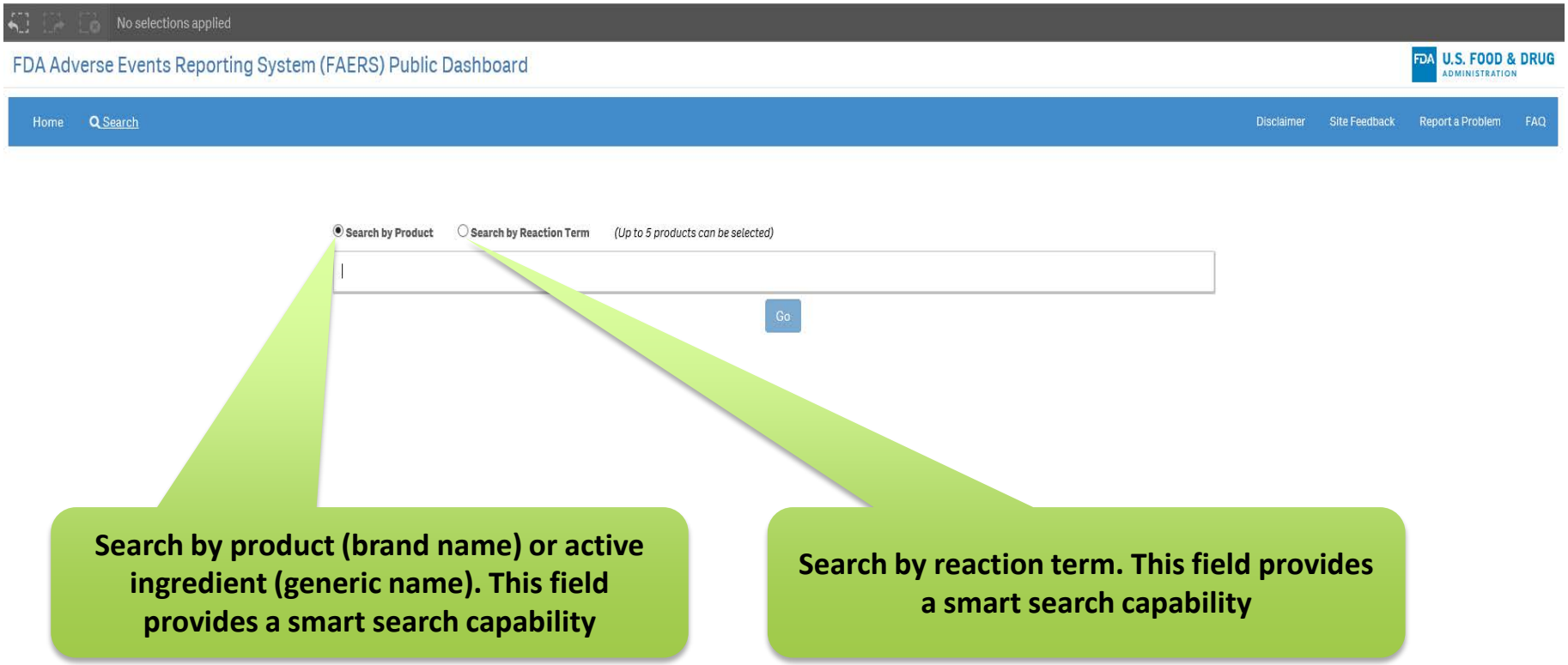
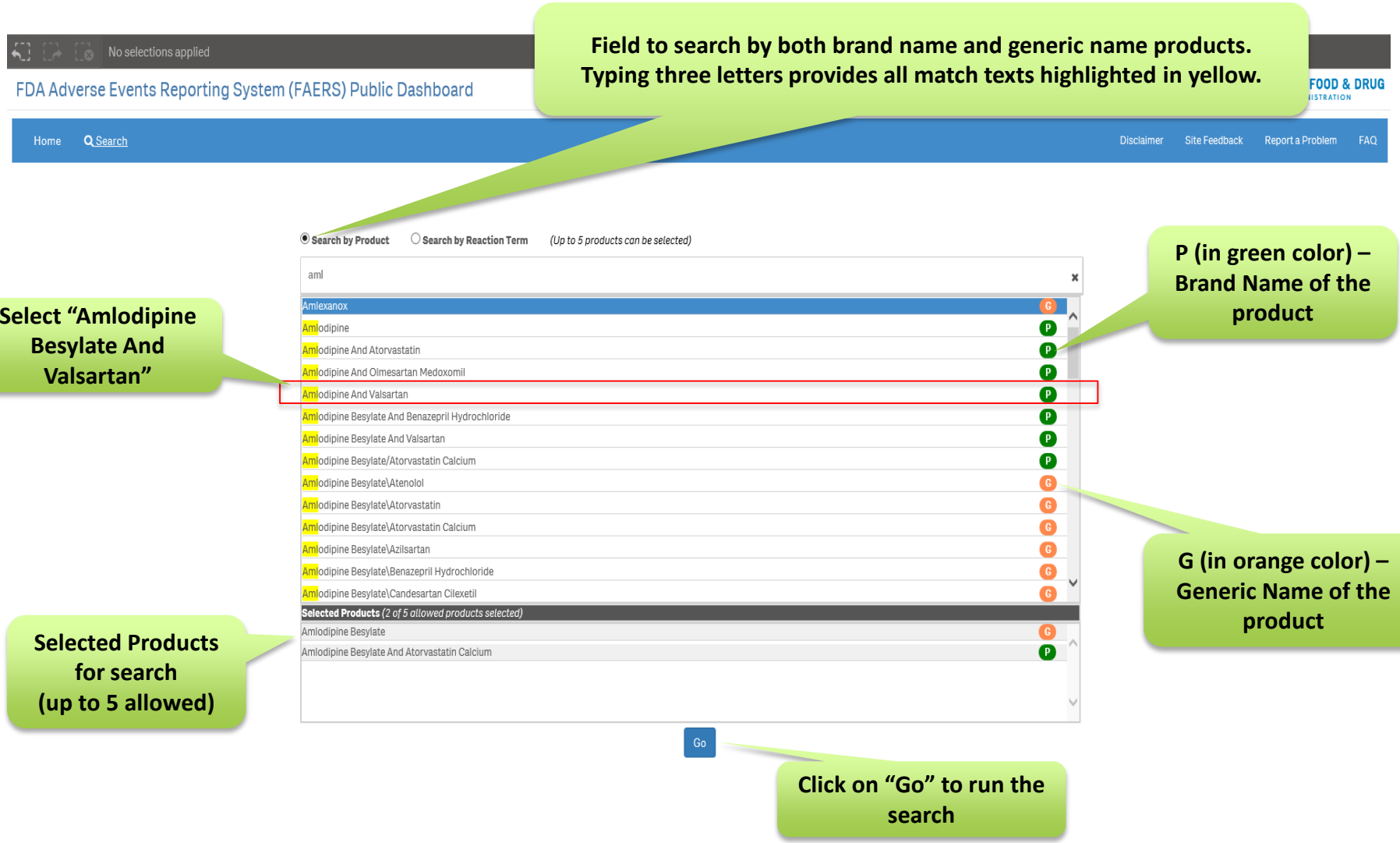
SEARCH BY PRODUCTS



SEARCH FOR PRODUCTS

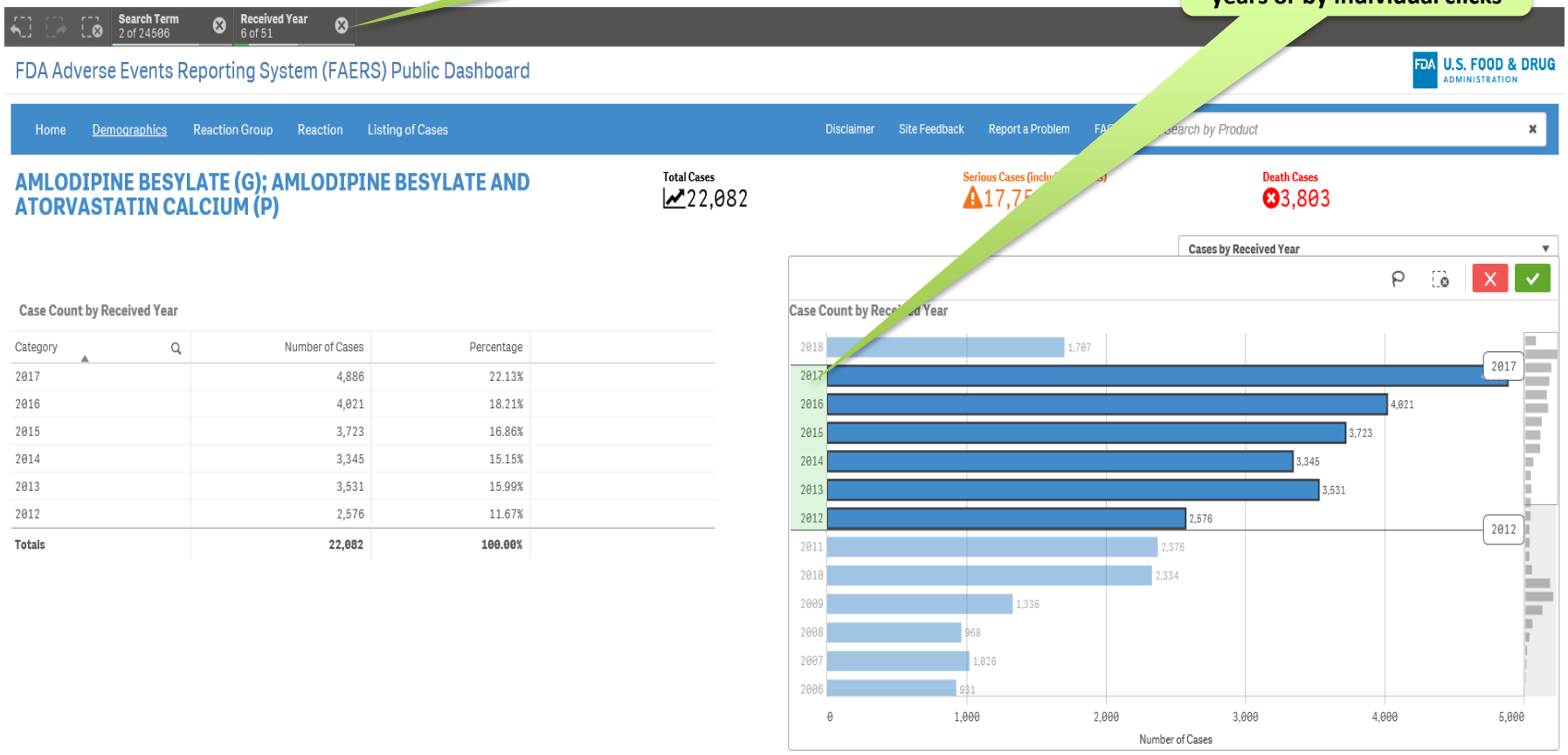


SEARCH PRODUCT RESULT

DEMOGRAPHICS

Filters applied for years

Drag the mouse to select years or by individual clicks



Data as of March 31, 2018

This page displays the number of cases identified for the product/reaction term 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

Search Term 2 of 24506 | Received Year 6 of 51

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 | Search by Product

AMLODIPINE BESYLATE (G); AMLODIPINE BESYLATE AND ATORVASTATIN CALCIUM (P)

Total Cases 22,082

Serious Cases (including deaths) 17,759

Death Cases 3,803

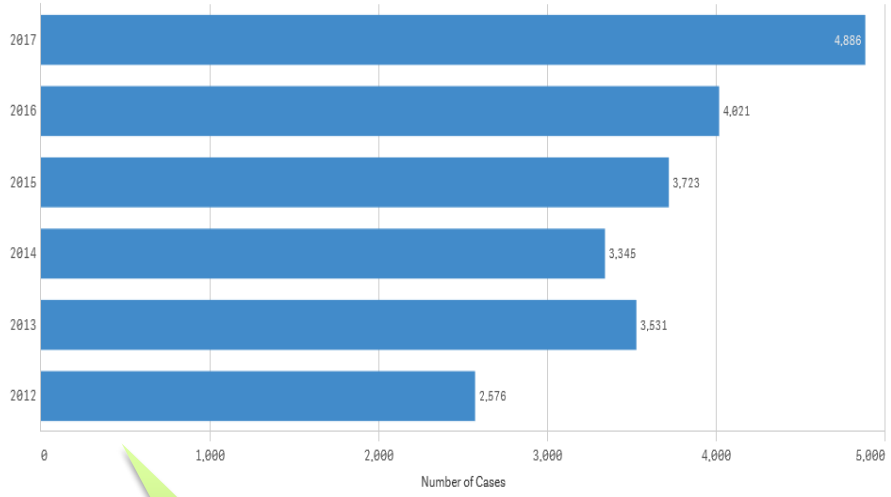
Cases by Received Year

Case Count by Received Year

Category	Number of Cases	Percentage
2017	4,886	22.13%
2016	4,021	18.21%
2015	3,723	16.86%
2014	3,345	15.15%
2013	3,531	15.99%
2012	2,576	11.67%
Totals	**22,082**	**100.00%**

Case by years - tabular view

Case Count by Received Year



Data as of March 31, 2018

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

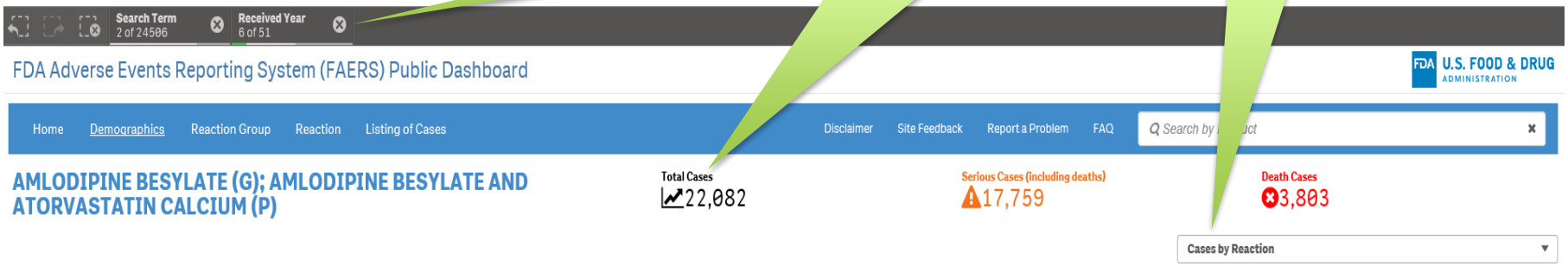
Case by years - graphical view

DEMOGRAPHICS

Years filter applied from 2012 to 2017

Total number of cases for the 2012 to 2017

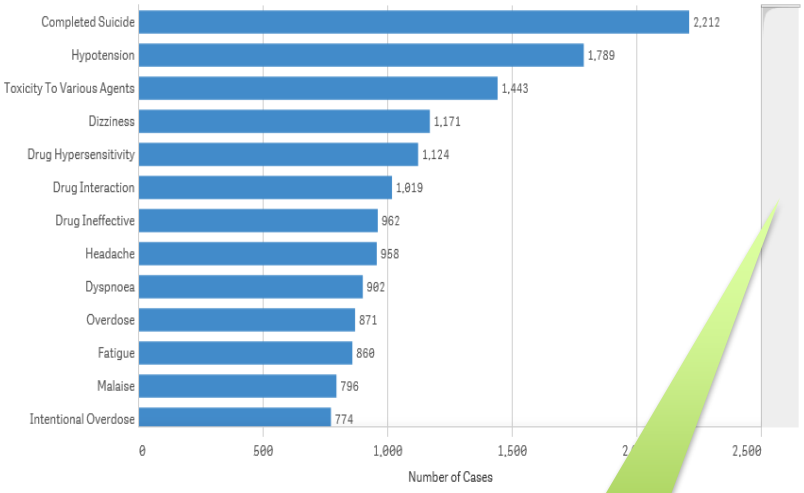
Cases by Reactions



Case Count by Reaction

Category	Number of Cases	Percentage
Completed Suicide	2,212	10.02%
Hypotension	1,789	8.10%
Toxicity To Various Agents	1,443	6.53%
Dizziness	1,171	5.30%
Drug Hypersensitivity	1,124	5.09%
Drug Interaction	1,019	4.61%
Drug Ineffective	962	4.36%
Headache	958	4.34%
Dyspnoea	902	4.08%
Overdose	871	3.94%
Fatigue	860	3.89%
Malaise	796	3.60%
Intentional Overdose	774	3.51%
Totals	**22,082**	**100.00%**

Case Count by Reaction



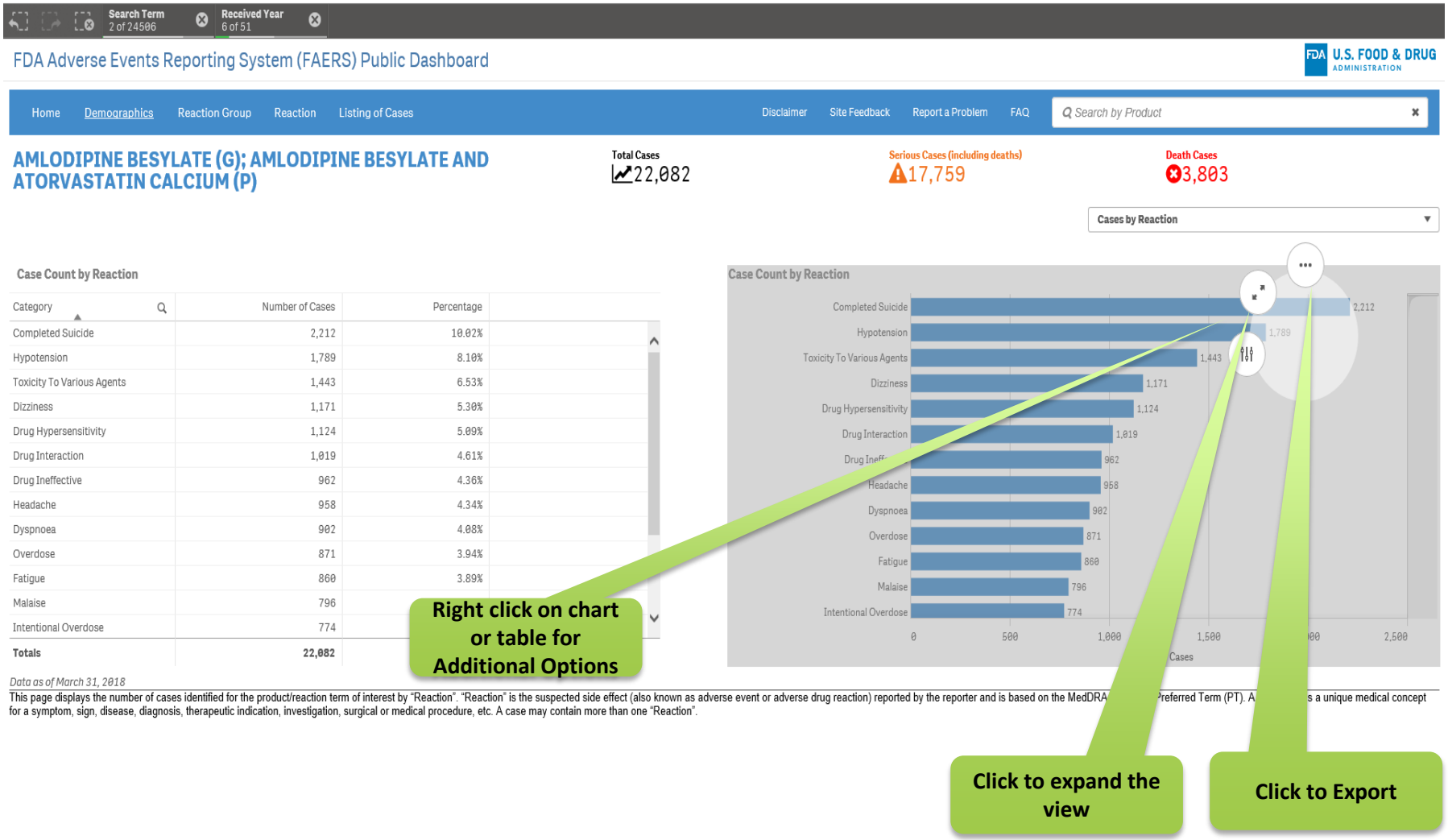
Data as of March 31, 2018

This page displays the number of cases "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 "R unique medical concept for a symptom, sign, disease, diagnosis, ical procedure, etc. A case may contain more than one "Reaction".

Reactions listed in descending order

Scrollbar to view all reactions

DEMOGRAPHICS

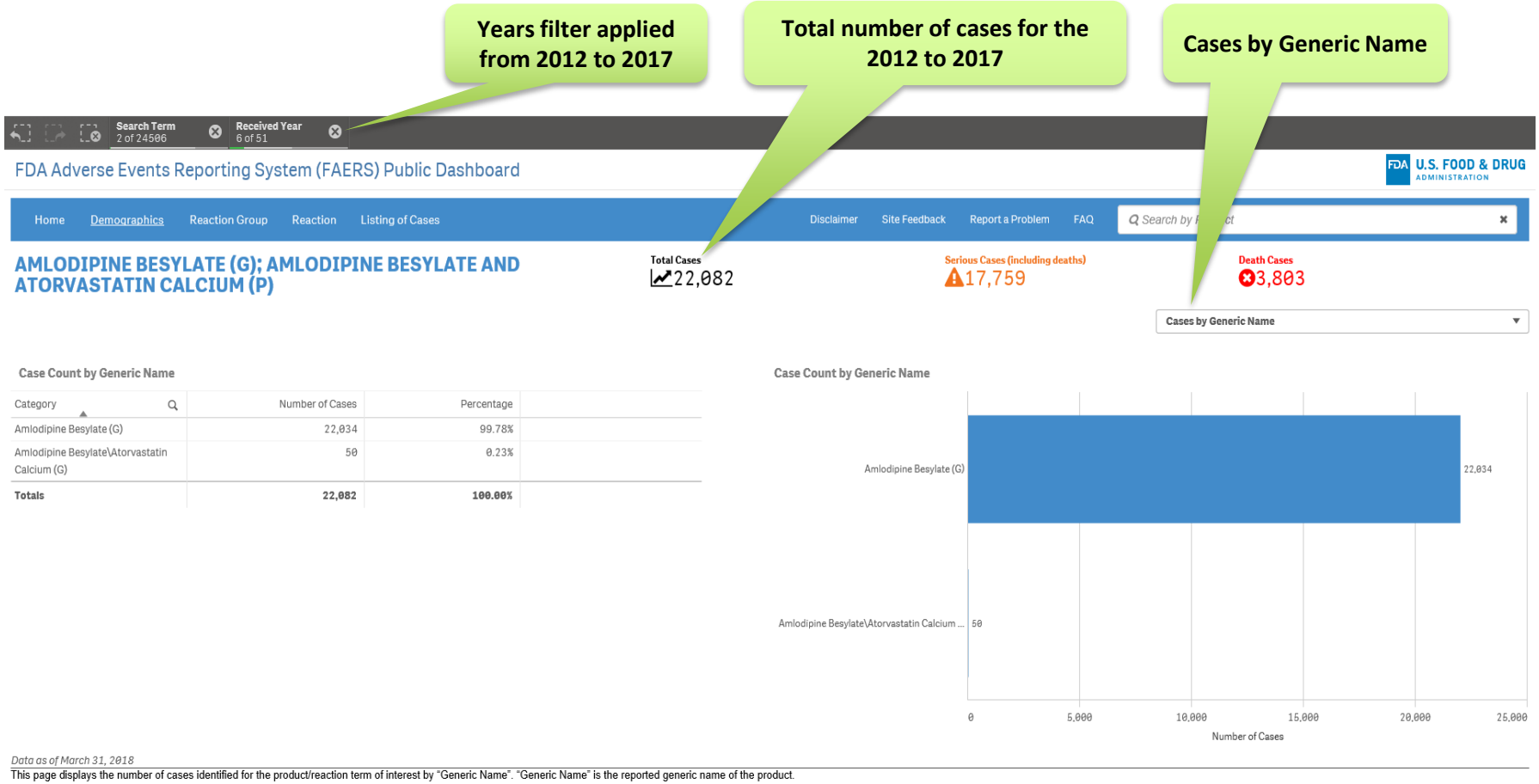


Right click on chart or table for Additional Options

Click to expand the view

Click to Export

DEMOGRAPHICS



Data as of March 31, 2018

This page displays the number of cases identified for the product/reaction term of interest by "Generic Name". "Generic Name" is the reported generic name of the product.

DEMOGRAPHICS

Years filter applied from 2012 to 2017

Total number of cases for the 2012 to 2017

Cases by Age Group

Search Term 2 of 24586 | Received Year 6 of 51

FDA Adverse Events Reporting System (FAERS) Public Dashboard

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Home | Demographics | Reaction Group | Reaction | Listing of Cases | Disclaimer | Site Feedback | Report a Problem | FAQ | Search by Product

AMLODIPINE BESYLATE (G); AMLODIPINE BESYLATE AND ATORVASTATIN CALCIUM (P)

Total Cases 22,082

Serious Cases (including deaths) 17,759

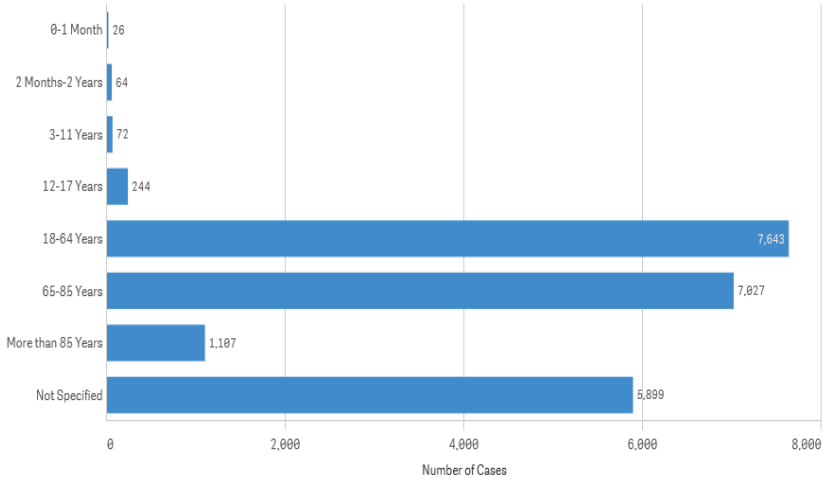
Death Cases 3,803

Cases by Age Group

Case Count by Age Group

Category	Number of Cases	Percentage
0-1 Month	26	0.12%
2 Months-2 Years	64	0.29%
3-11 Years	72	0.33%
12-17 Years	244	1.10%
18-64 Years	7,643	34.61%
65-85 Years	7,027	31.82%
More than 85 Years	1,107	5.01%
Not Specified	5,899	26.71%
Totals	**22,082**	**100.00%**

Case Count by Age Group



Data as of March 31, 2018

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

DEMOGRAPHICS

Years filter applied from 2012 to 2017

Total number of cases for the 2012 to 2017

Cases by Sex

Search Term 2 of 24506 | Received Year 6 of 51

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Serious Cases (including deaths) 17,759

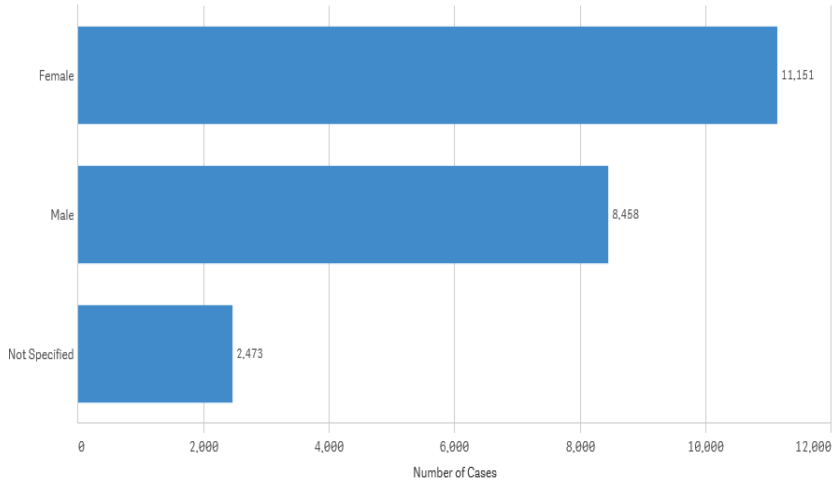
Death Cases 3,803

Cases by Sex

Case Count by Sex

Category	Number of Cases	Percentage
Female	11,151	50.50%
Male	8,458	38.30%
Not Specified	2,473	11.20%
Totals	**22,082**	**100.00%**

Case Count by Sex



Data as of March 31, 2018

This page displays the number of cases identified for the product/reaction term 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

Search Term 2 of 24506 | Received Year 6 of 51

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AMLODIPINE BESYLATE (G); AMLODIPINE BESYLATE AND ATORVASTATIN CALCIUM (P)

Total Cases 22,082

Serious Cases (including deaths) 17,759

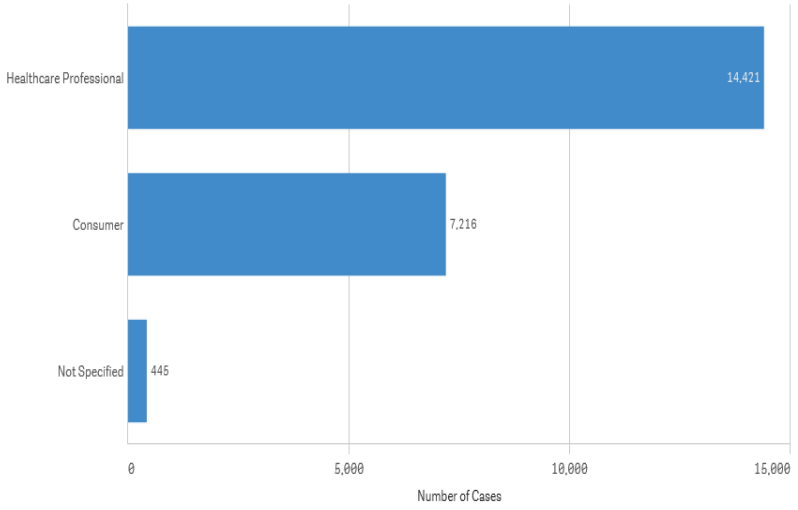
Death Cases 3,803

Cases by Reporter Type

Case Count by Reporter

Category	Number of Cases	Percentage
Healthcare Professional	14,421	65.31%
Consumer	7,216	32.68%
Not Specified	445	2.02%
Totals	**22,082**	**100.00%**

Case Count by Reporter



Data as of March 31, 2018

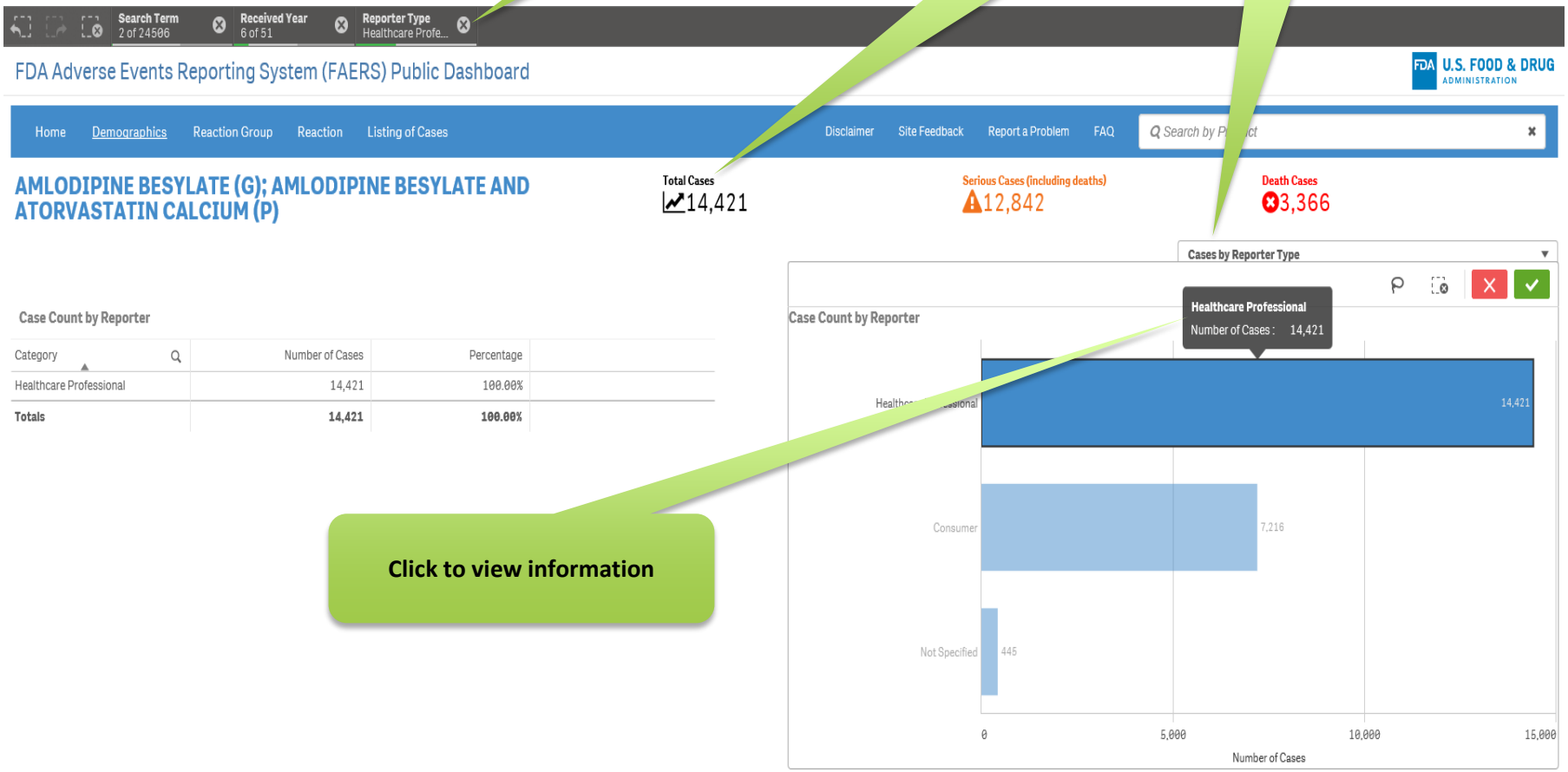
This page displays the report counts based on the occupation of the Reporter, the person who submitted the report to FDA or the person who submitted the report to the manufacturer (who then sent the report to FDA). Physicians and pharmacists are the Healthcare Professionals (HCPs) who submit reports 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

Total number of cases based on applied filter

Cases by Reporter Type

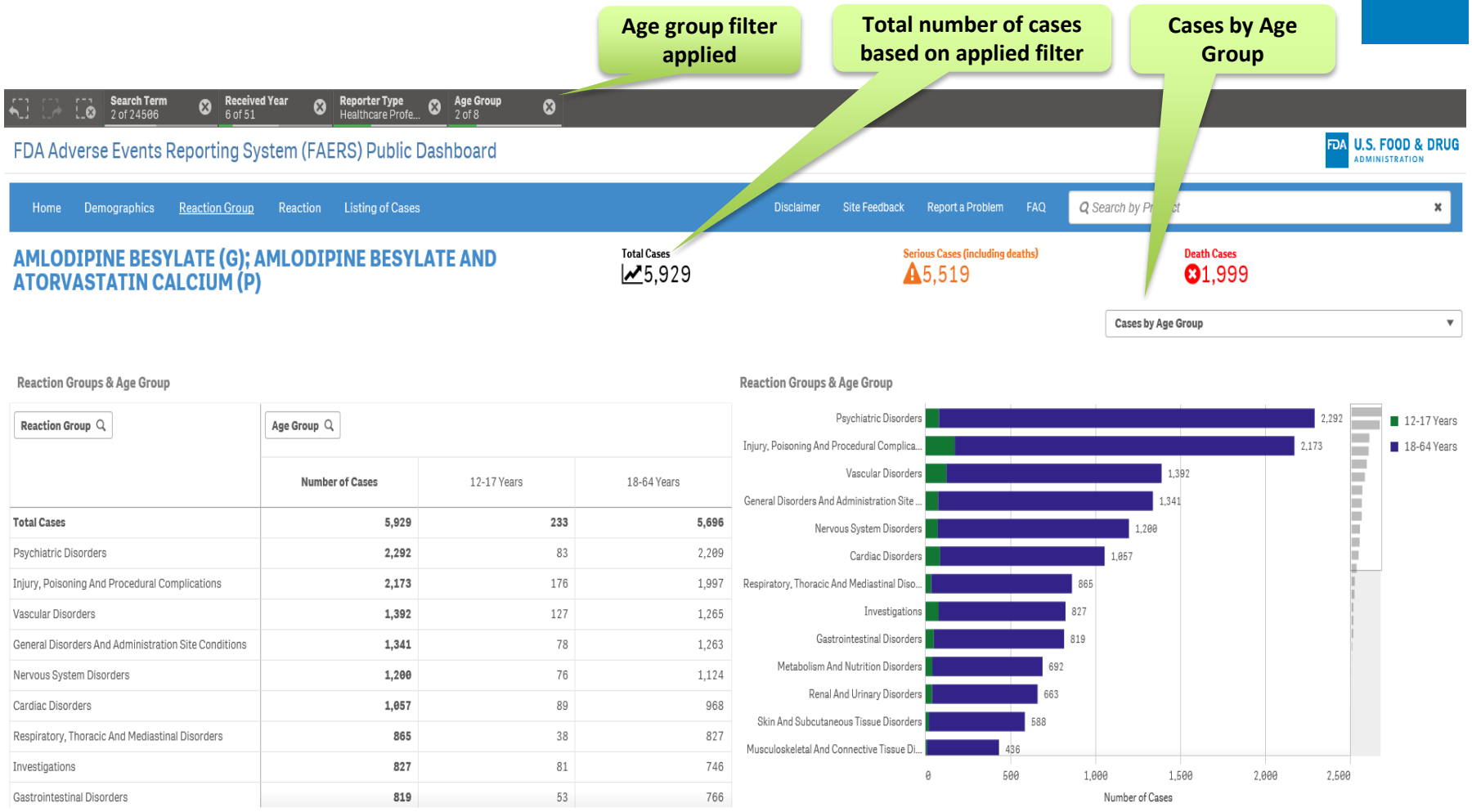


Click to view information

Data as of March 31, 2018

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.

REACTION GROUP



Data as of March 31, 2018

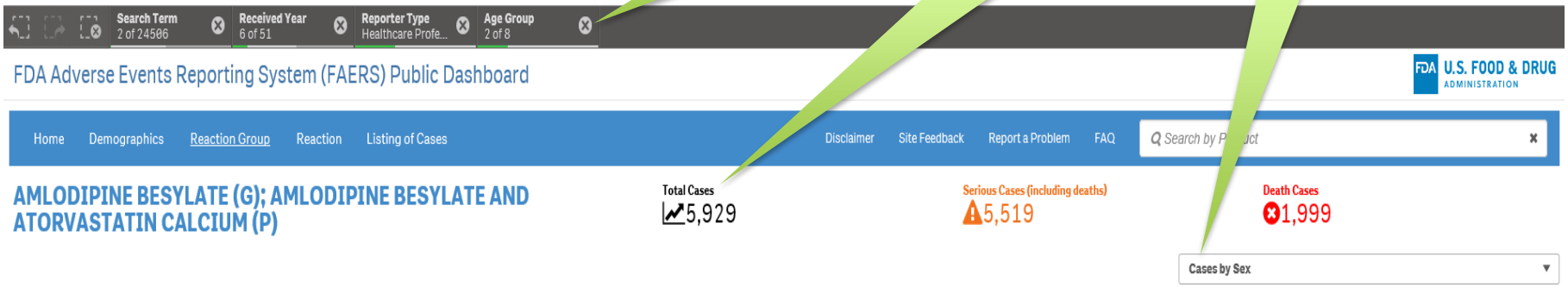
This page displays the number of cases identified for the product/reaction term of interest by "Reaction Group" and the reported age of the patient. "Reaction Groups" are based on a classification of the side effect (also known as "Reaction" or adverse event or adverse drug reaction), using the MedDRA 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

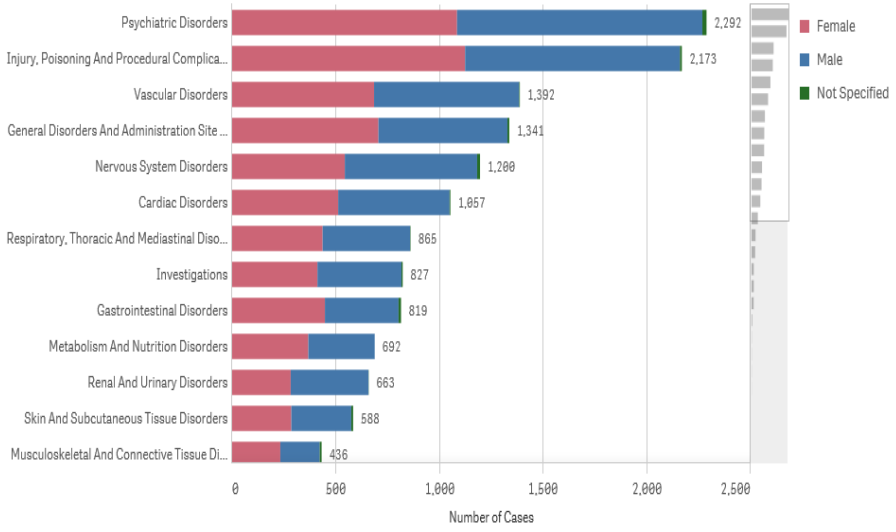
Cases by Sex



Reaction Groups & Sex

Reaction Group	Number of Cases	Female	Male	Not Specified
Total Cases	**5,929**	**2,889**	**2,975**	**65**
Psychiatric Disorders	**2,292**	1,089	1,183	20
Injury, Poisoning And Procedural Complications	**2,173**	1,128	1,036	9
Vascular Disorders	**1,392**	689	700	3
General Disorders And Administration Site Conditions	**1,341**	710	622	9
Nervous System Disorders	**1,200**	548	638	14
Cardiac Disorders	**1,057**	516	537	4
Respiratory, Thoracic And Mediastinal Disorders	**865**	441	422	2
Investigations	**827**	416	405	6
Gastrointestinal Disorders	**819**	452	355	12

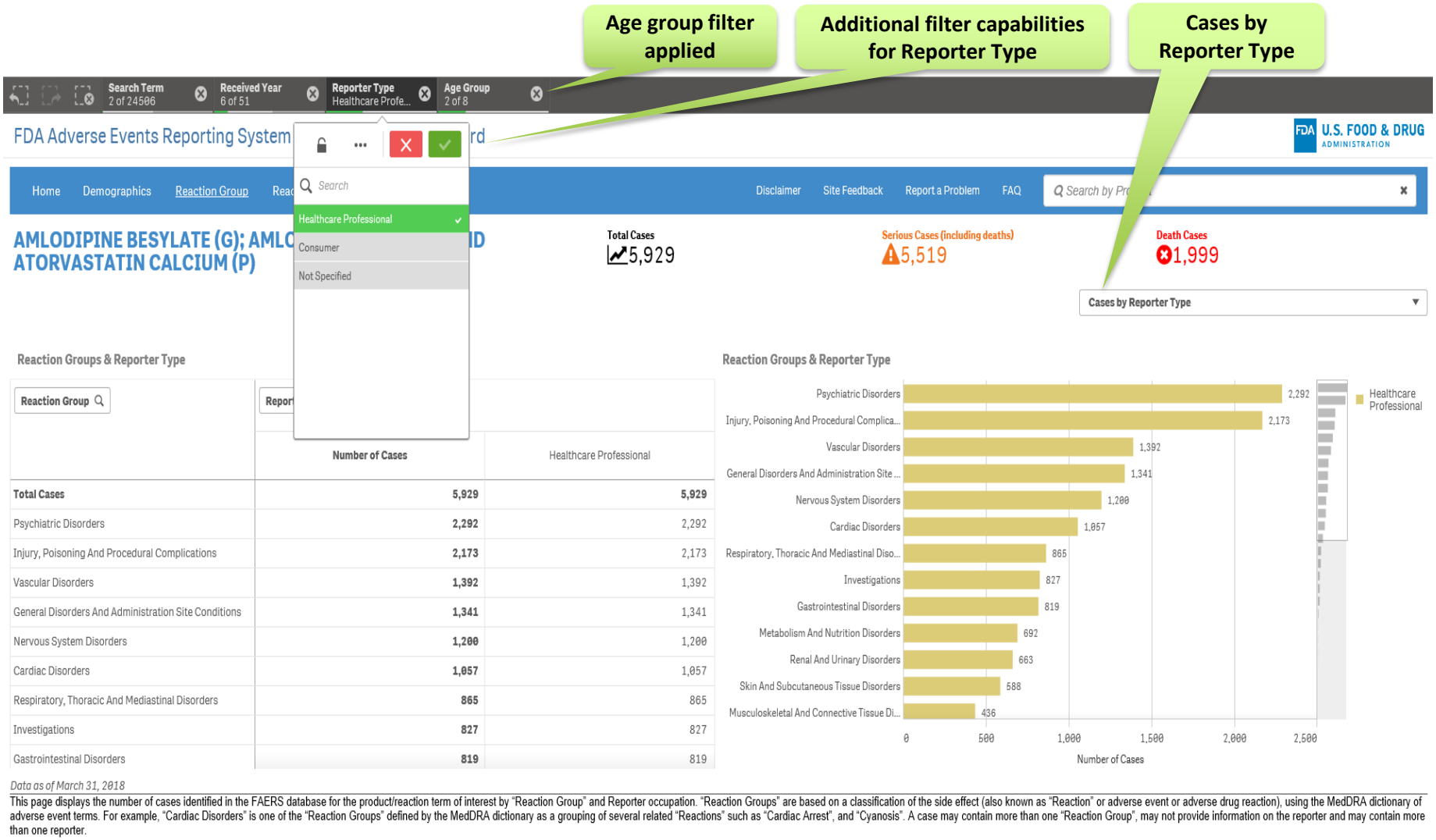
Reaction Groups & Sex



Data as of March 31, 2018

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

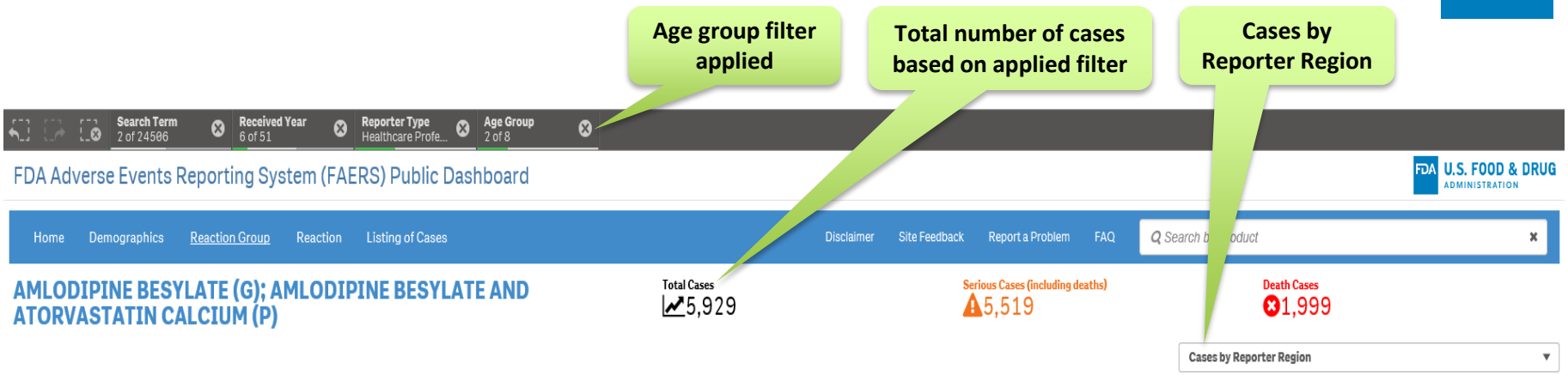
REACTION GROUP



Data as of March 31, 2018

This page displays the number of cases identified in the FAERS database for the product/reaction term of interest by "Reaction Group" and Reporter occupation. "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", may not provide information on the reporter and may contain more than one reporter.

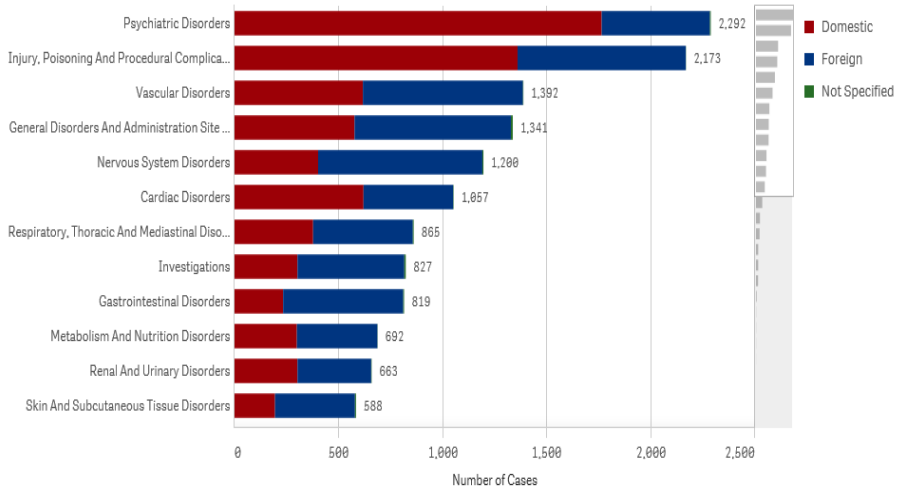
REACTION GROUP



Reaction Groups & Reporter Region

Reaction Group	Number of Cases	Domestic	Foreign	Not Specified
Total Cases	**5,929**	**3,158**	**2,754**	**17**
Psychiatric Disorders	**2,292**	1,768	520	4
Injury, Poisoning And Procedural Complications	**2,173**	1,364	808	1
Vascular Disorders	**1,392**	621	769	2
General Disorders And Administration Site Conditions	**1,341**	581	751	9
Nervous System Disorders	**1,200**	406	789	5
Cardiac Disorders	**1,057**	624	431	2
Respiratory, Thoracic And Mediastinal Disorders	**865**	382	479	4
Investigations	**827**	307	513	7

Reaction Groups & Reporter Region



Data as of March 31, 2018

This page displays the number of cases identified in the FAERS database for the product/reaction term of interest by "Reaction Group" and region. "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". Region indicates the country where the event occurred or the country of the Reporter if event country information is not available. "Domestic" means that the country where event occurred or reporter's country is the United States. "Foreign" means that the country where the event occurred or the country of the Reporter is outside the United States. "Not Specified" means that there was no data in the report that documented the geographic region of the event or the Reporter.

REACTION

Cases by Reaction Year vs Outcomes

Search Term 2 of 24506 | Received Year 6 of 51 | Reporter Type Healthcare Profe... | Age Group 2 of 8 | Country Domestic | Reaction Group Vascular Disorders

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AMLODIPINE BESYLATE (G); AMLODIPINE BESYLATE AND ATORVASTATIN CALCIUM (P)

Total Cases 621

Serious Cases (including deaths) 597

Death Cases 67

Received Year vs Outcome

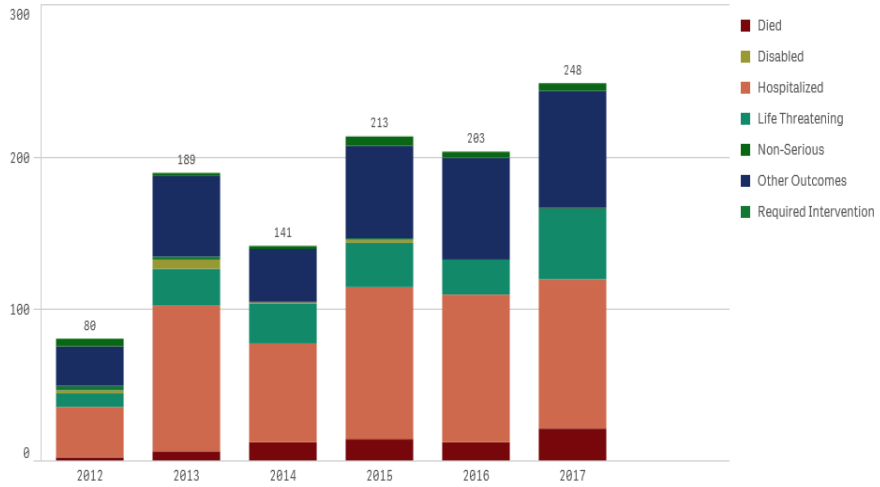
Total number of cases based on applied filter

Reaction Group and Reaction

Reaction Group | Reaction

		Number of Cases
Total Cases		**621**
Vascular Disorders	**Number of Cases**	**621**
	Hypotension	363
	Shock	203
	Hypertension	37
	Haemodynamic Instability	19
	Circulatory Collapse	16
	Blood Pressure Inadequately Controlled	15
	Orthostatic Hypotension	13
	Hypertensive Crisis	12

Outcome counts by Received Year

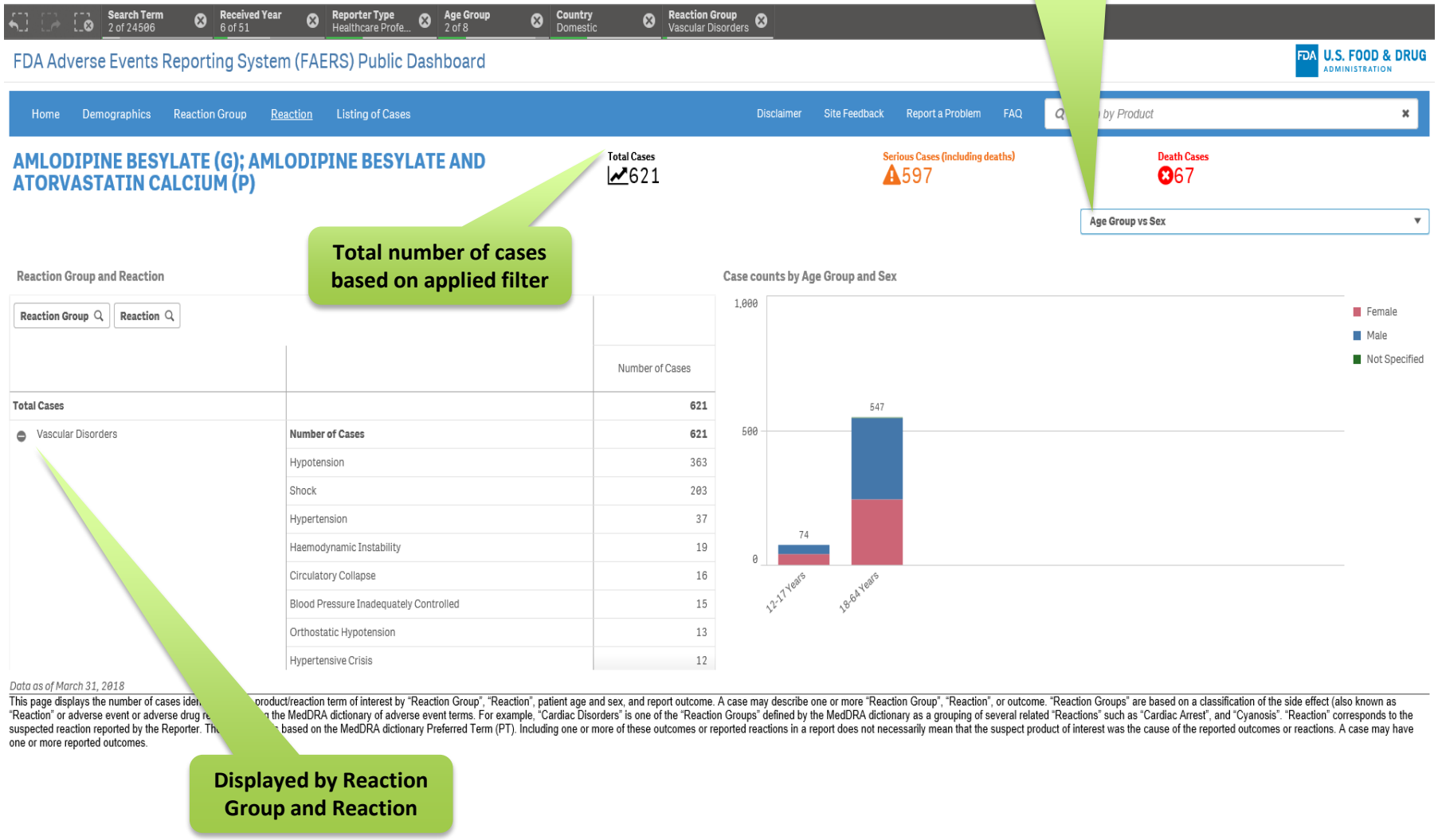


Data as of March 31, 2018

This page displays the number of cases identified for the product/reaction term of interest by "Reaction Group", "Reaction", patient age and sex, and report outcome. A case may describe one or more "Reaction Group", "Reaction", or outcome. "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". "Reaction" corresponds to the suspected reaction reported by the Reporter. The "Reaction" is based on the MedDRA dictionary Preferred Term (PT). Including 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. A case may have one or more reported outcomes.

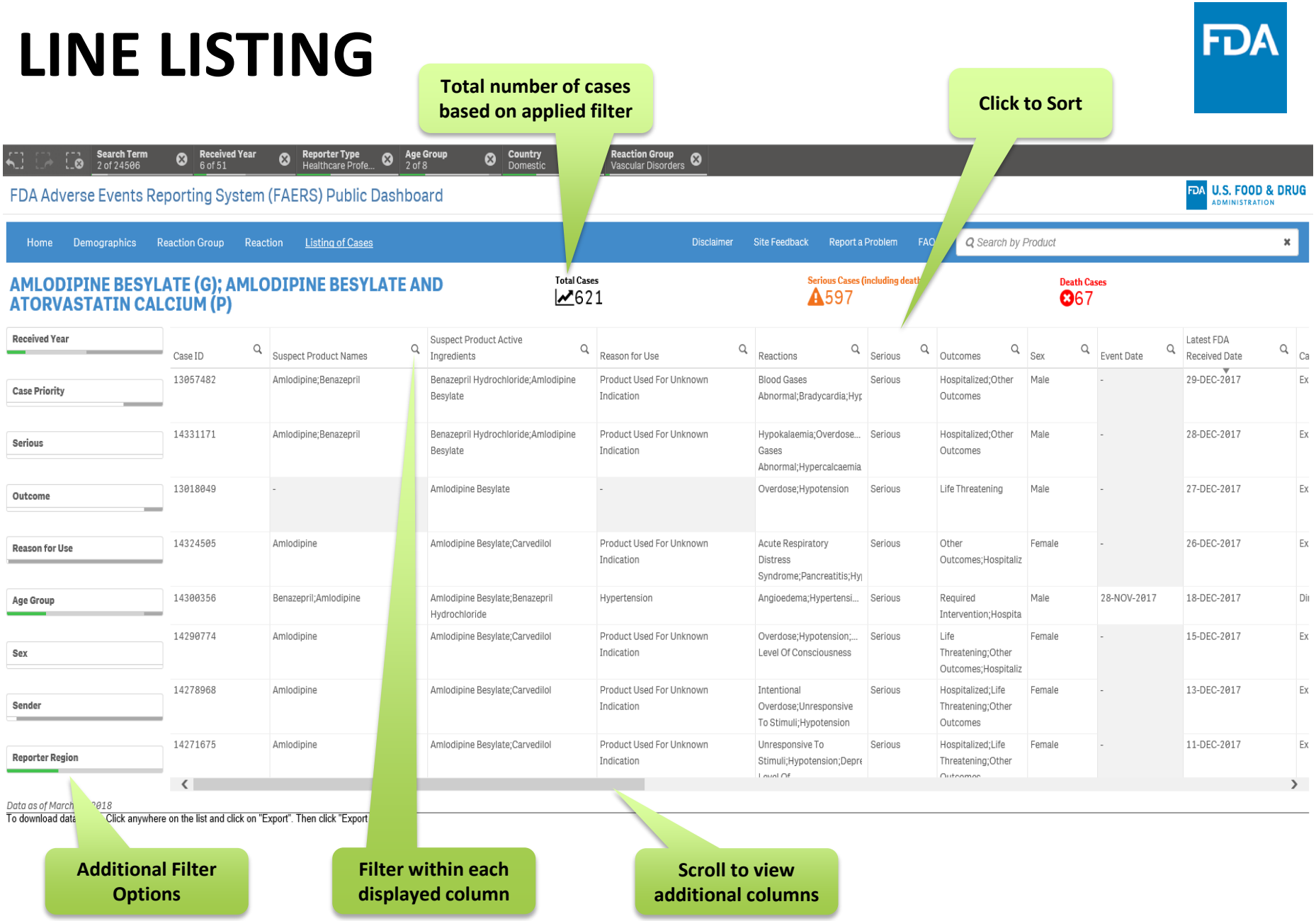
REACTION

Cases by Age Group vs Sex

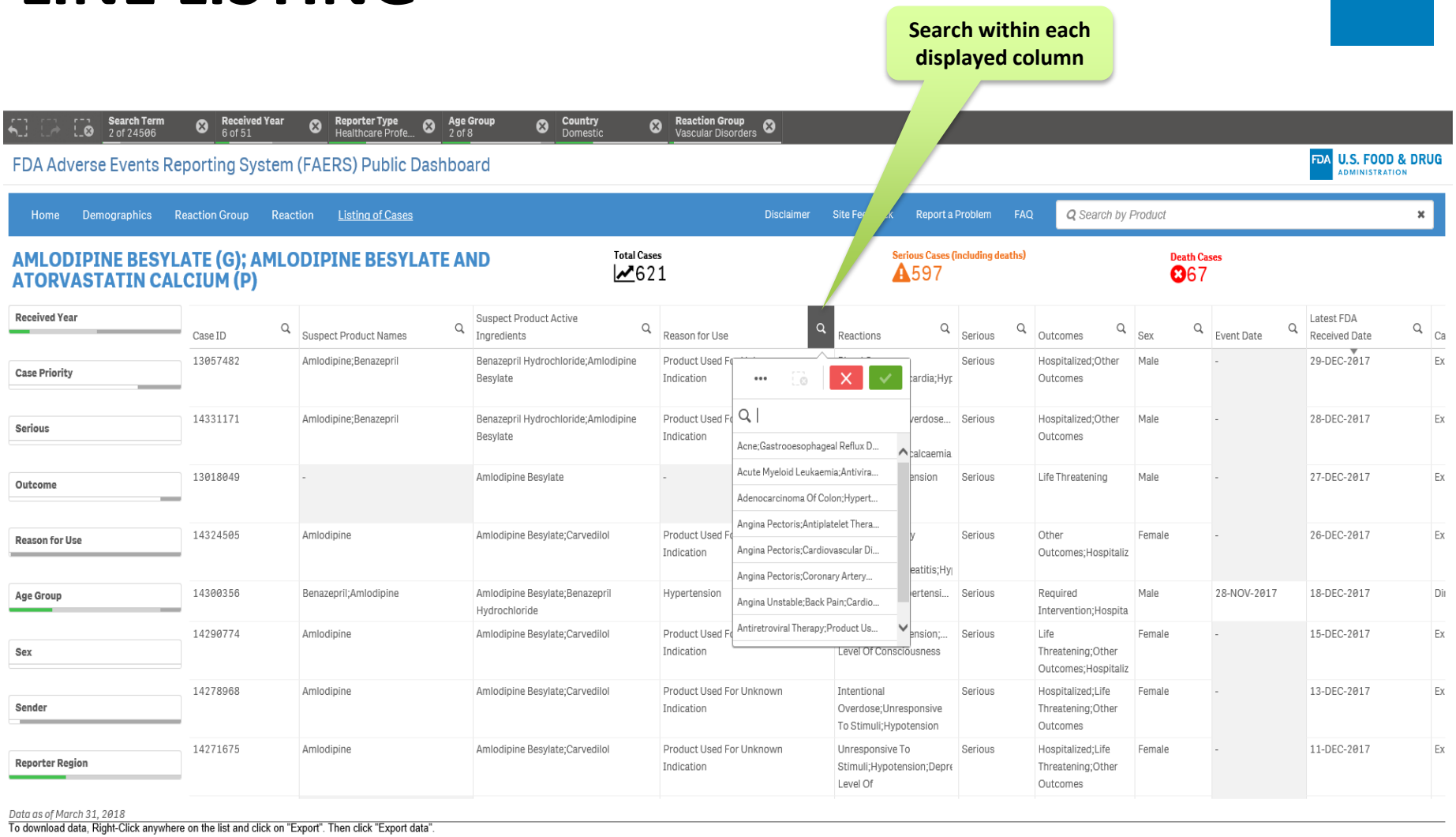


Displayed by Reaction Group and Reaction

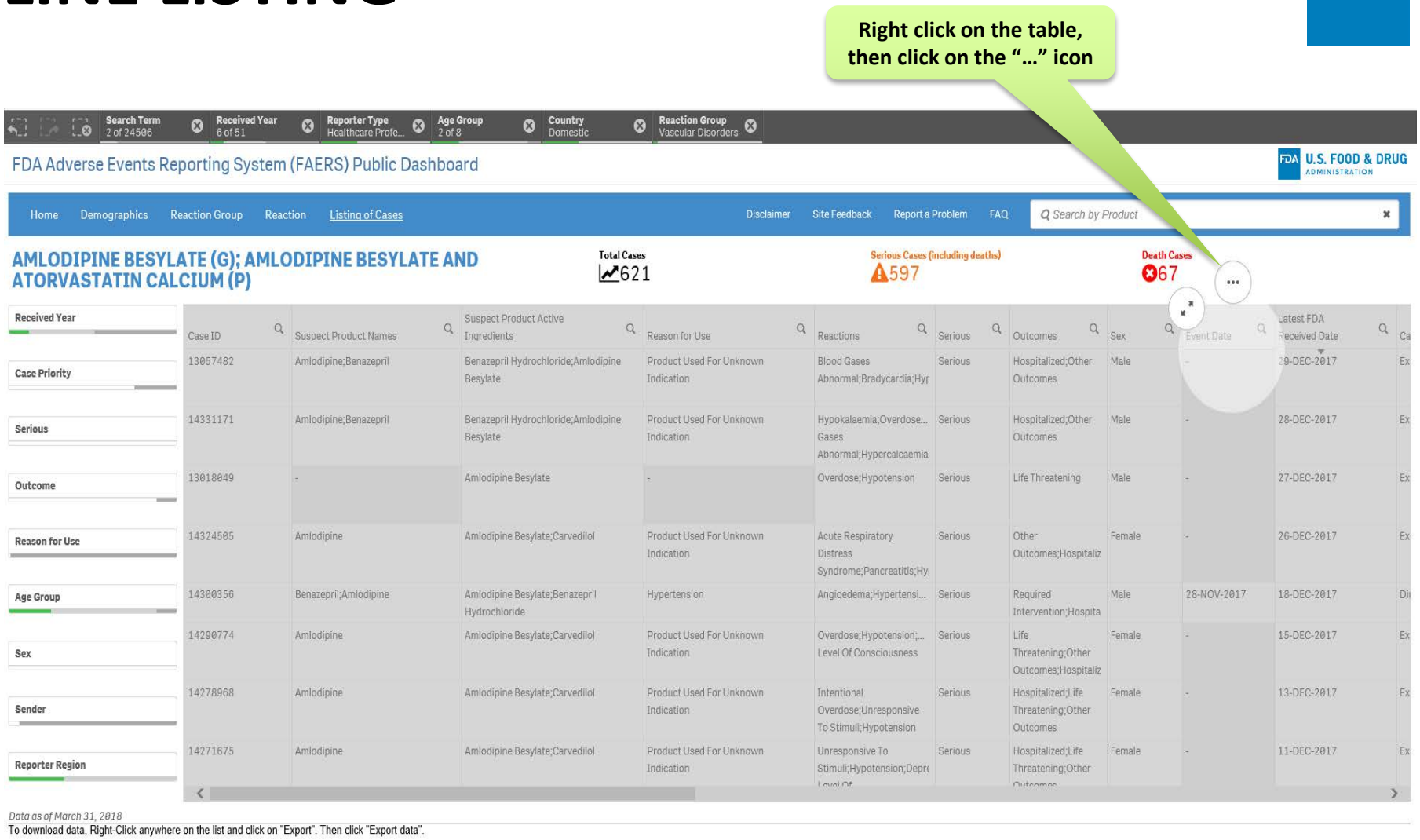
LINE LISTING



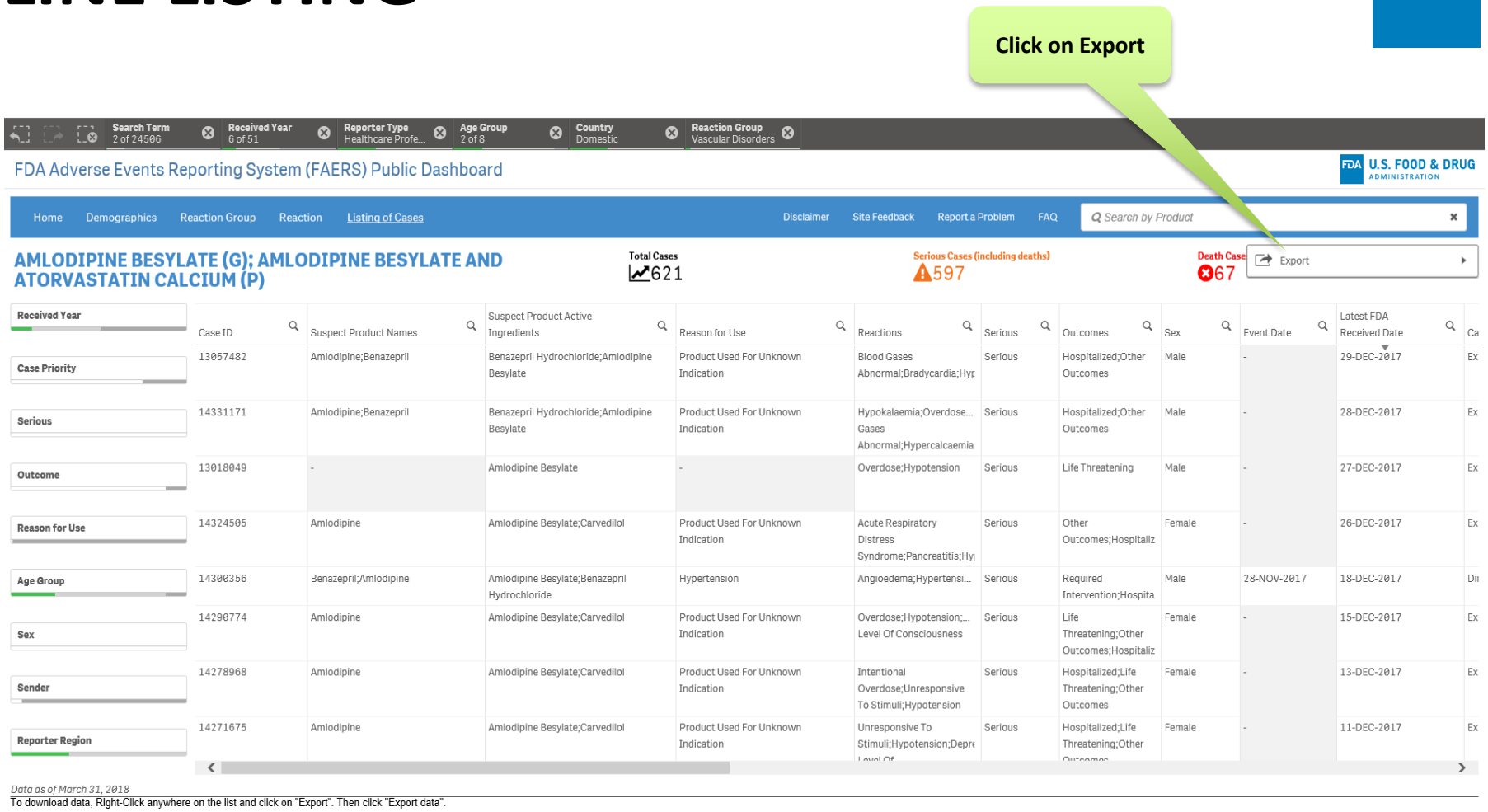
LINE LISTING



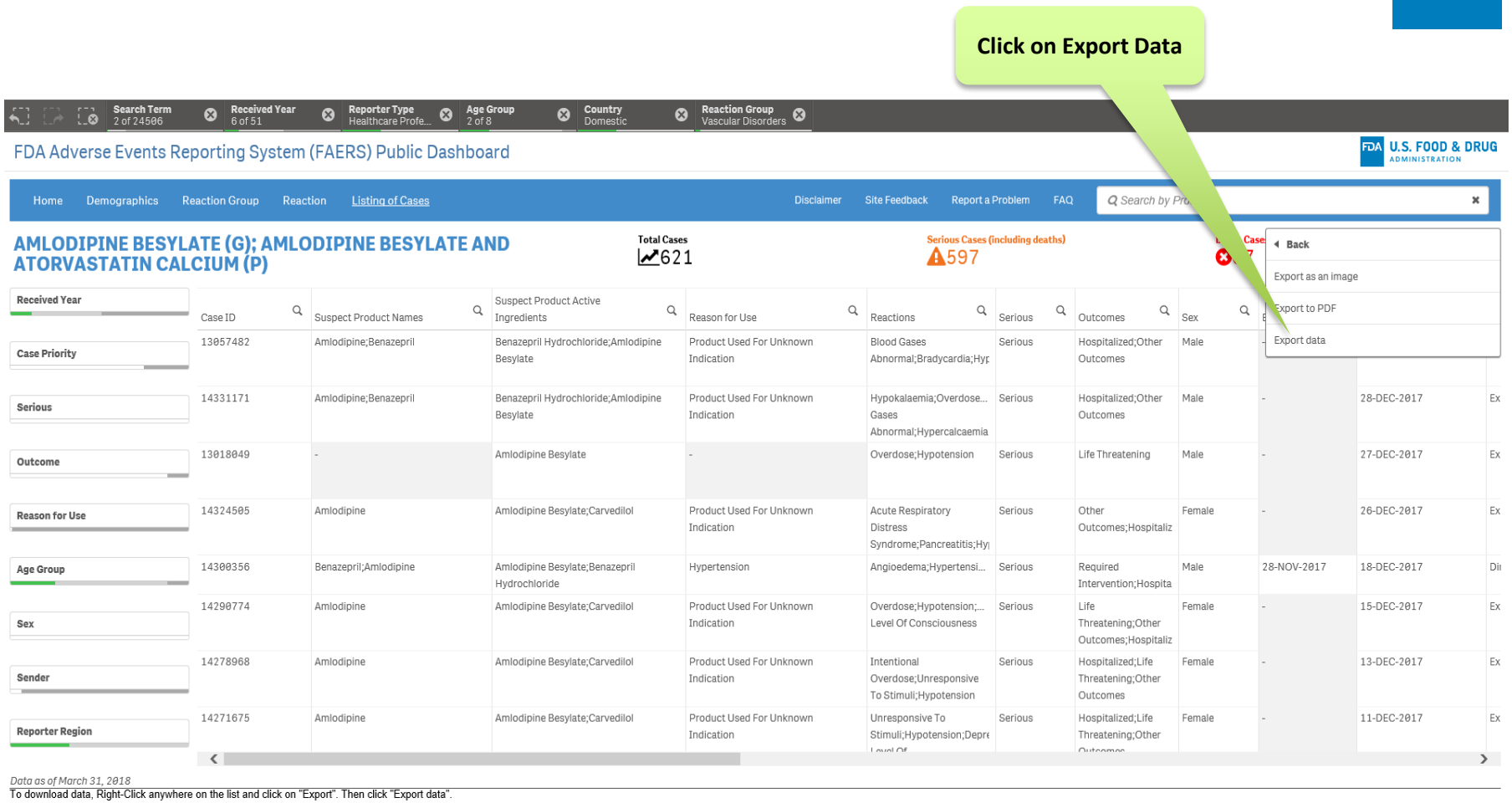
LINE LISTING



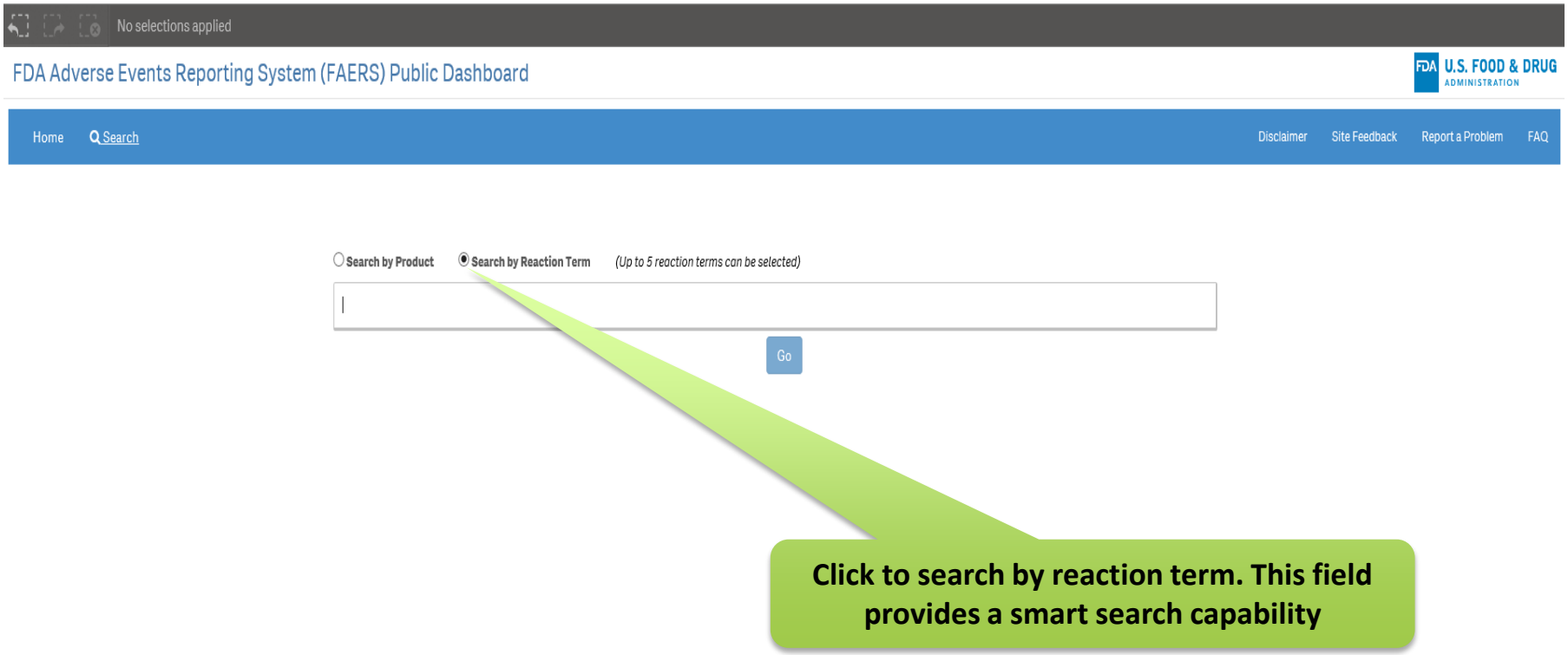
LINE LISTING



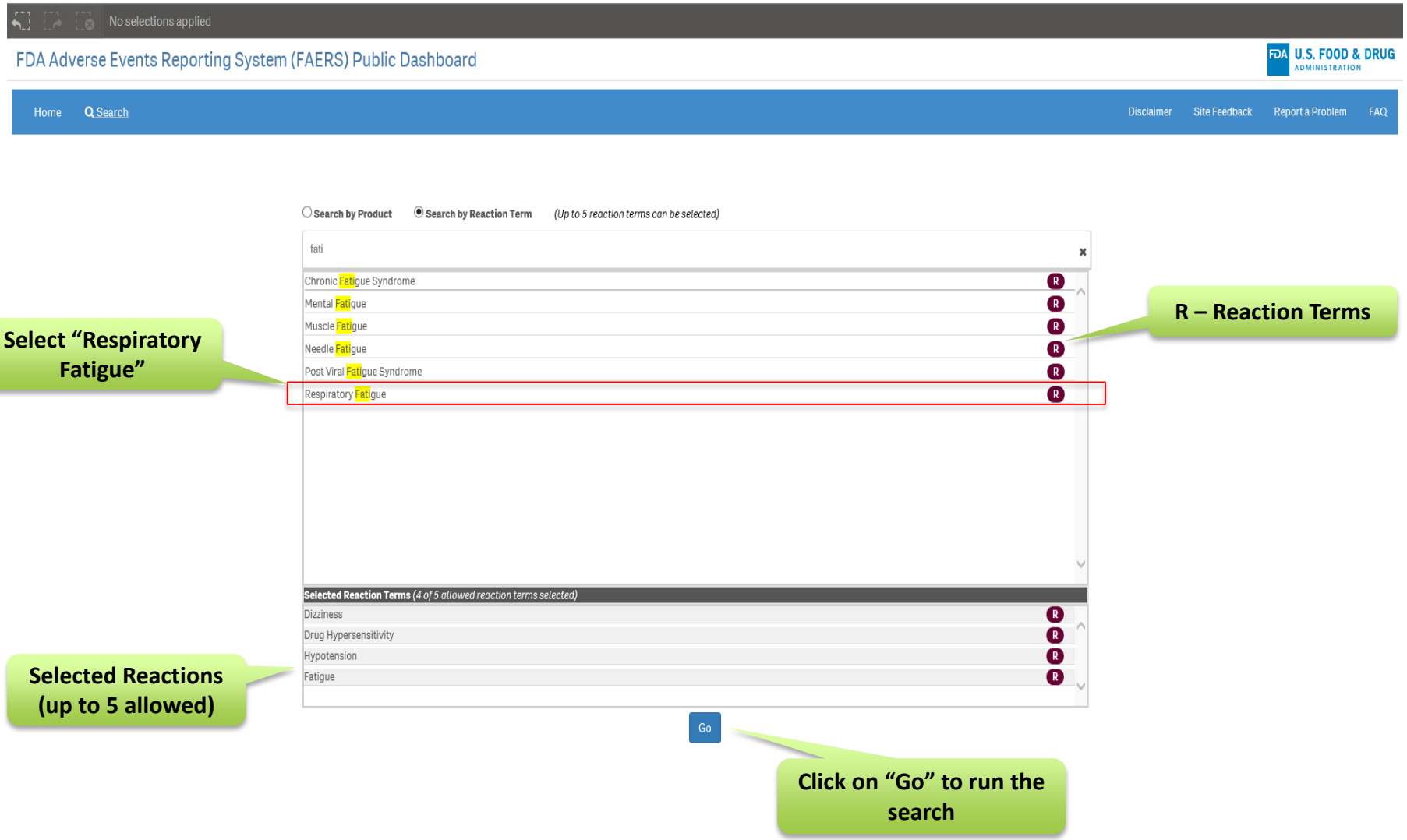
LINE LISTING



SEARCH BY REACTION TERMS



SEARCH BY REACTION TERMS



DEMOGRAPHICS

Cases by Product Name

Reaction Term 4 of 18768 | Received Year 6 of 51 | Country Domestic | Age Group 3 of 8

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DIZZINESS; DRUG HYPERSENSITIVITY; FATIGUE; HYPOTENSION

Total Cases 225,706

Serious Cases (including deaths) 89,412

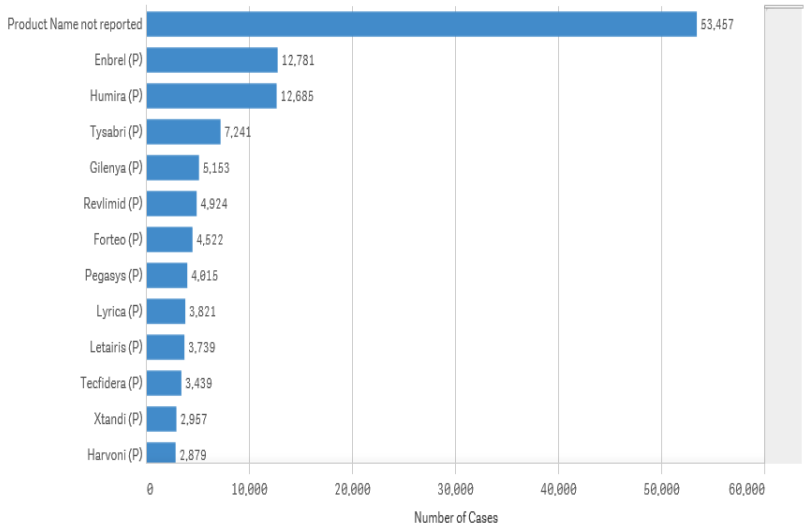
Death Cases 6,949

Cases by Product Name

Case Count by Product Name

Category	Number of Cases	Percentage
Product Name not reported	53,457	23.68%
Enbrel (P)	12,781	5.66%
Humira (P)	12,685	5.62%
Tysabri (P)	7,241	3.21%
Gilenya (P)	5,153	2.28%
Revlimid (P)	4,924	2.18%
Forteo (P)	4,522	2.00%
Pegasys (P)	4,015	1.78%
Lyrica (P)	3,821	1.69%
Letairis (P)	3,739	1.66%
Tecfidera (P)	3,439	1.52%
Xtandi (P)	2,957	1.31%
Harvoni (P)	2,879	1.28%
Totals	**225,706**	**100.00%**

Case Count by Product Name



Data as of March 31, 2018

This page displays the number of cases identified for the product/reaction term of interest by "Product Name". "Product Name" is the reported trade or brand name of the product. "Reported as Generic" indicates cases for which only generic name of the product was reported and trade or brand name was not reported.

DEMOGRAPHICS

Cases by Generic Name

Reaction Term 4 of 18768 | Received Year 6 of 51 | Country Domestic | Age Group 3 of 8

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DIZZINESS; DRUG HYPERSENSITIVITY; FATIGUE; HYPOTENSION

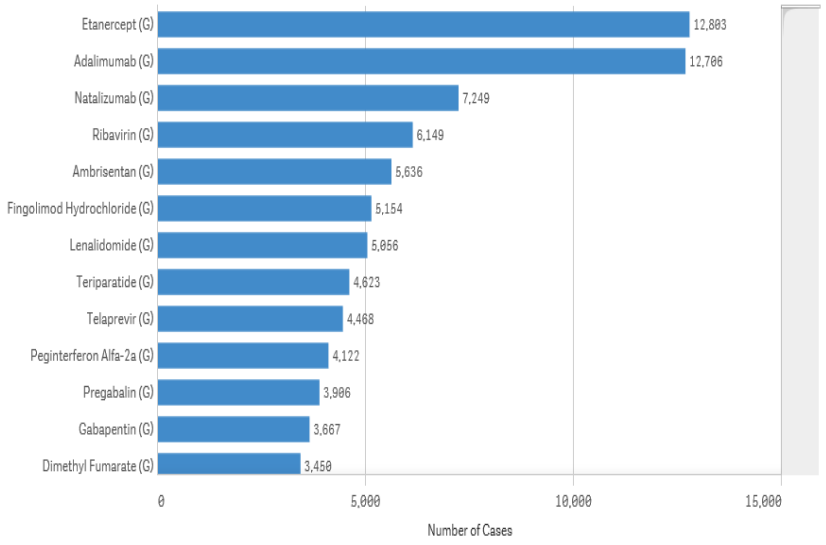
Total Cases 225,706 | Serious Cases (including deaths) 89,412 | Death Cases 6,949

Cases by Generic Name

Case Count by Generic Name

Category	Number of Cases	Percentage
Etanercept (G)	12,803	5.67%
Adalimumab (G)	12,706	5.63%
Natalizumab (G)	7,249	3.21%
Ribavirin (G)	6,149	2.72%
Ambrisentan (G)	5,636	2.50%
Fingolimod Hydrochloride (G)	5,154	2.28%
Lenalidomide (G)	5,056	2.24%
Teriparatide (G)	4,623	2.05%
Telaprevir (G)	4,468	1.98%
Peginterferon Alfa-2a (G)	4,122	1.83%
Pregabalin (G)	3,906	1.73%
Gabapentin (G)	3,667	1.62%
Dimethyl Fumarate (G)	3,450	1.53%
Totals	**225,706**	**100.00%**

Case Count by Generic Name



Data as of March 31, 2018

This page displays the number of cases identified for the product/reaction term of interest by "Generic Name". "Generic Name" is the reported generic name of the product.

CONCLUSION

- FAERS dashboard gives the consumer, healthcare professionals 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 FAERS reports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