U.S. FOOD & DRUG ADMINISTRATION

"FDA Adverse Event Reporting System (FAERS) Public Dashboard"

Date: January 30th, 2018

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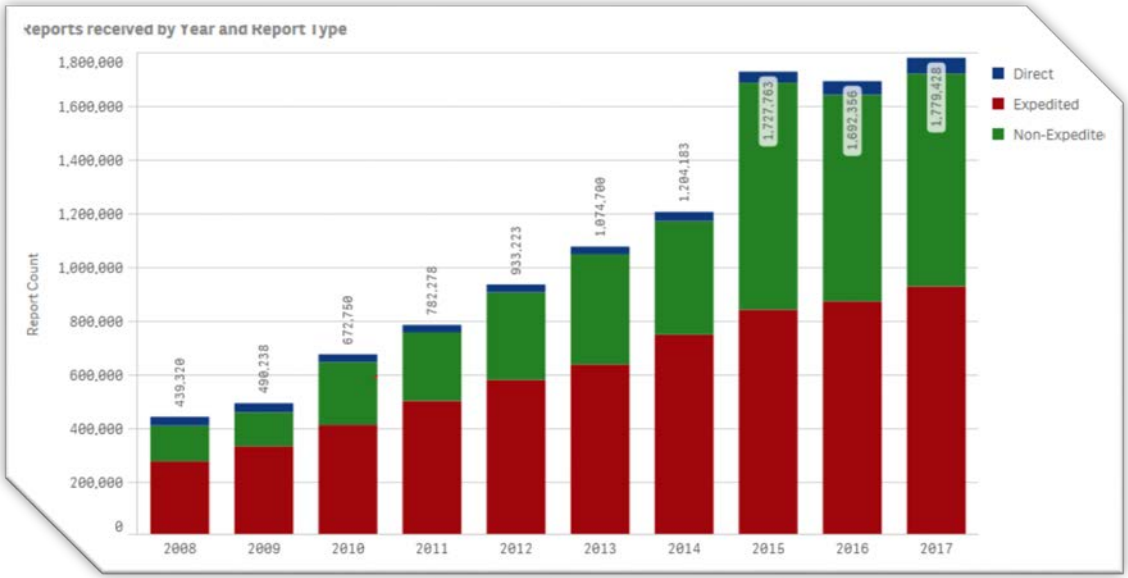
LEARNING OBJECTIVES

- ❑ 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:

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.

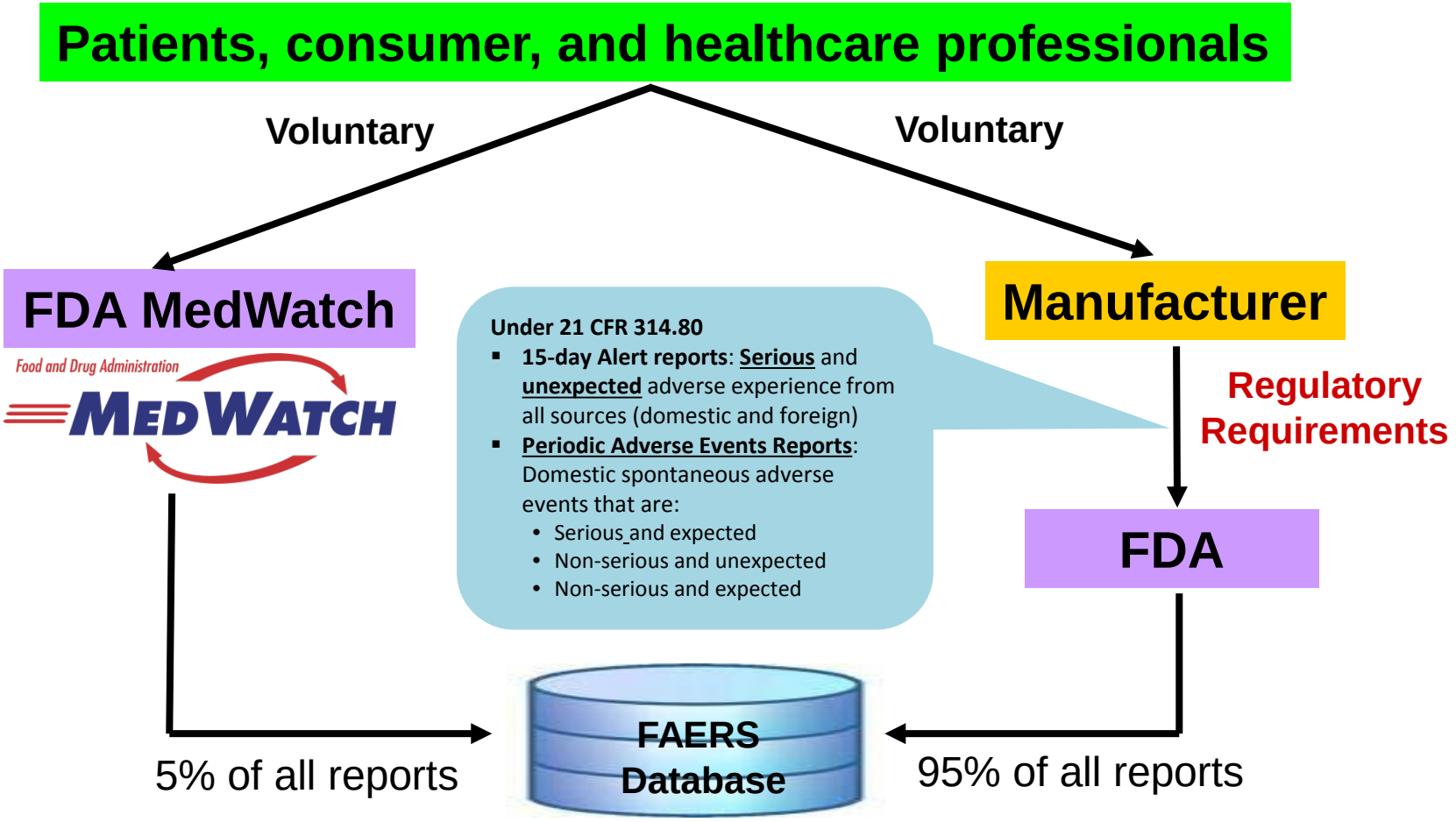
SPONTANEOUS REPORTS

- 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

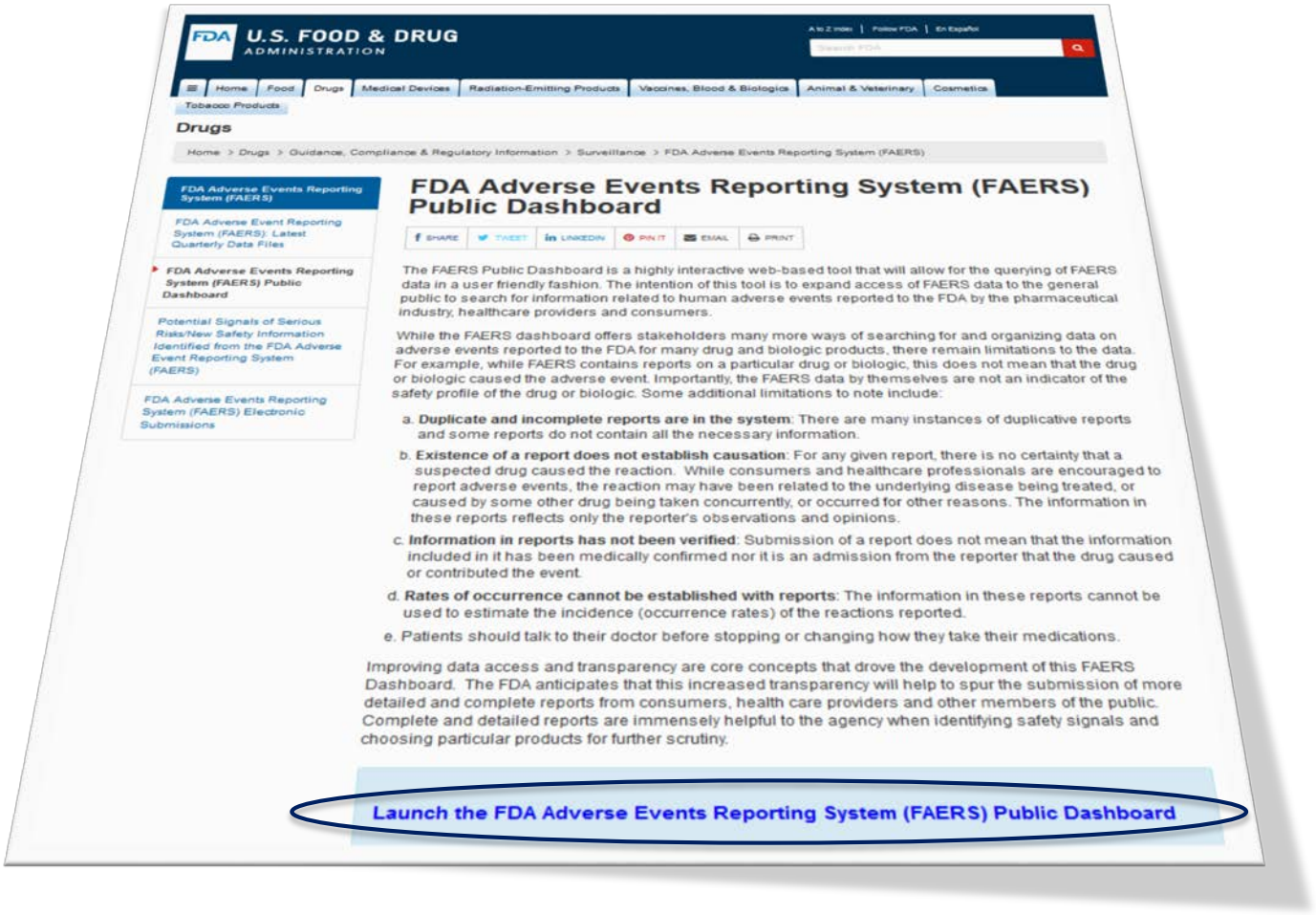
FAERS IS LESS USEFUL FOR

- 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

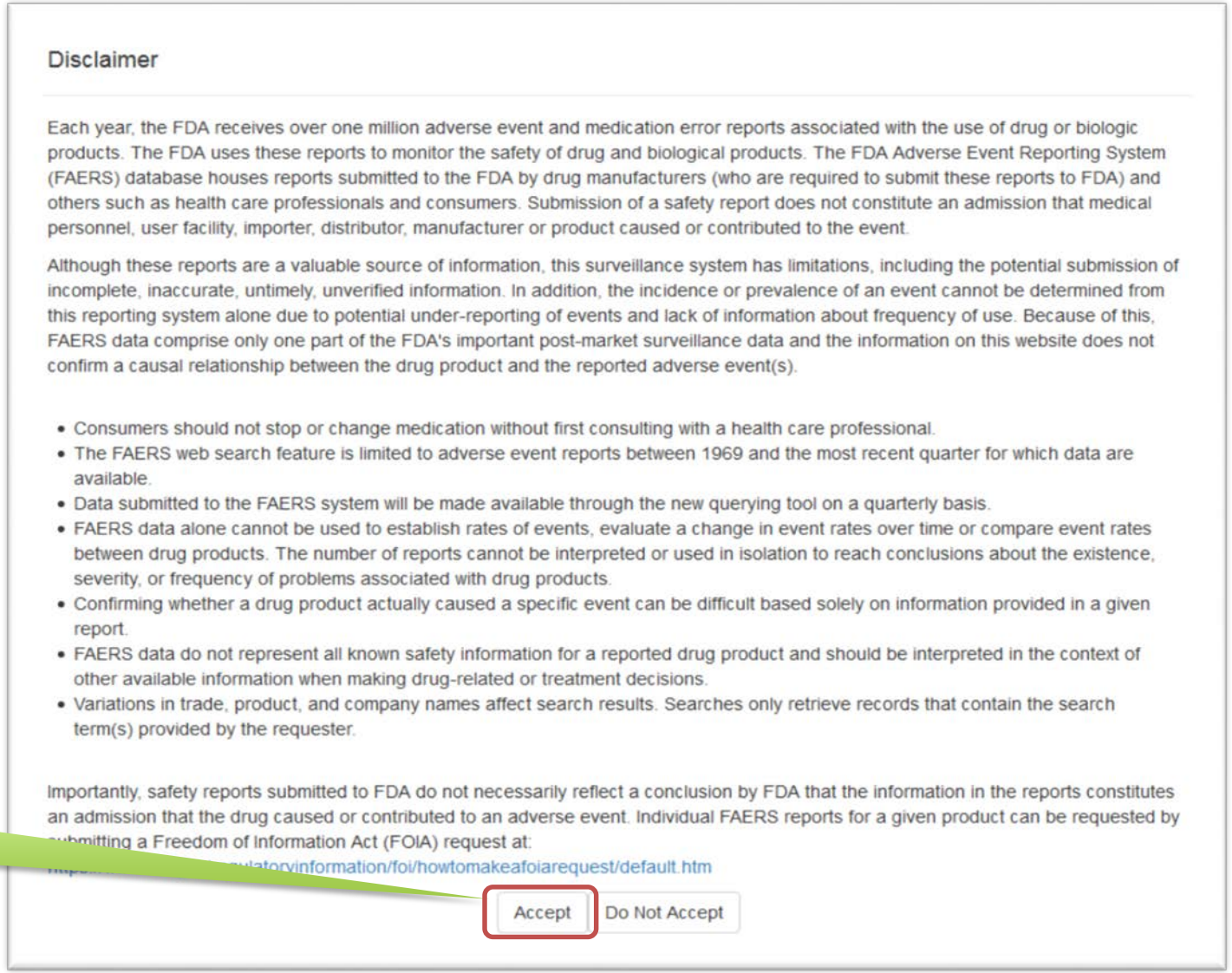
FAERS PUBLIC DASHBOARD

LAUNCH FAERS PUBLIC DASHBOARD

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



DISCLAIMER



Click on "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

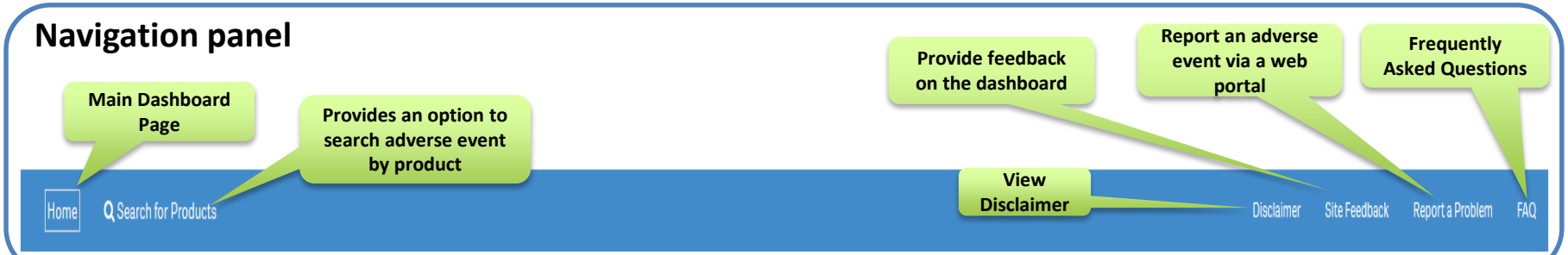
b. No

- 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

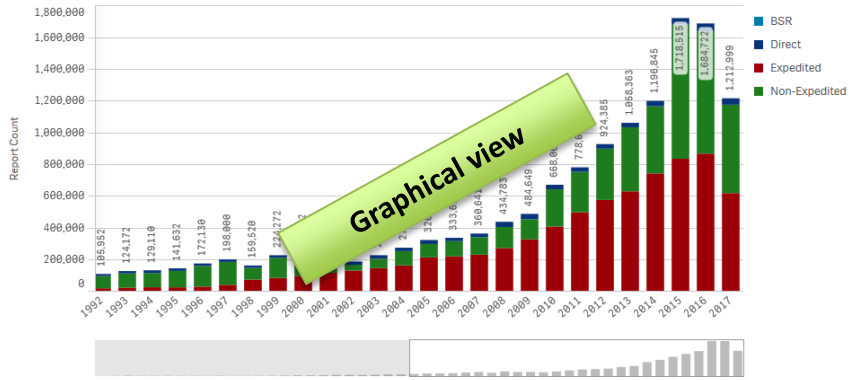
Reports received by Year and Report Type

Year ▾ | Category ▾

	Total Reports	Expedited	Non-Expedited	Direct	BSR
Total Reports	**14,160,191**	**7,437,939**		**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**		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 Page

Selected filter criteria

Provides an option to search adverse event by product

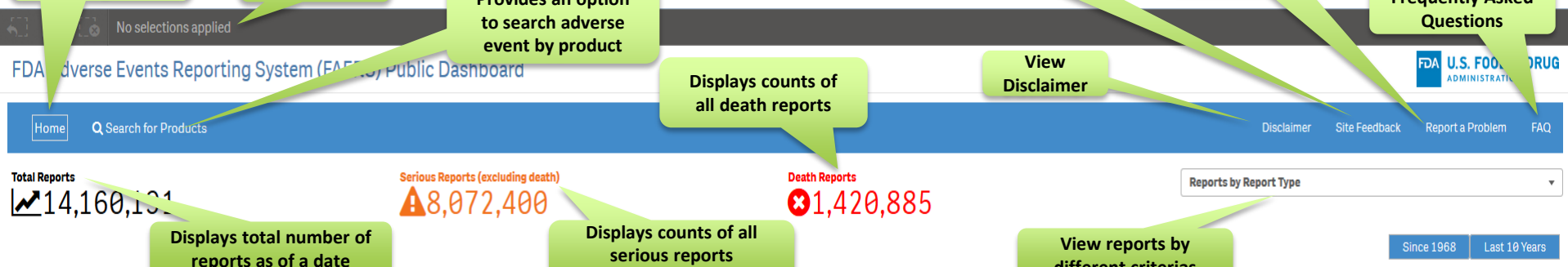
Provide feedback on the dashboard

Report an adverse event via a web portal

Frequently Asked Questions

Displays counts of all death reports

View Disclaimer



Displays total number of reports as of a date

Displays counts of all serious reports (excluding death reports)

View reports by different criterias

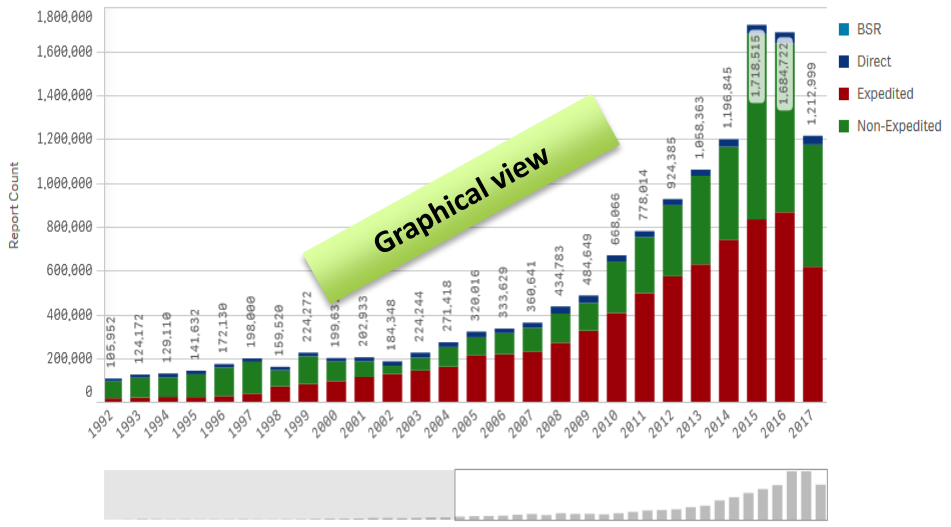
Reports received by Year and Report Type

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	845,052	41,539	-
2014	1,196,845	739,581	1,150	34,114	-
2013	1,058,363	626,692	403,368	28,303	-
2012	924,385		323,059	28,866	-
2011	778,014		255,058	27,995	-
2010	668,066		234,578	28,902	-
2009	484,649		324,421	126,138	34,090	-
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	224,244		142,759	59,691	22,979	14

Tabular view

Reports received by Year and Report Type



Graphical view

Data as of August 31, 2017

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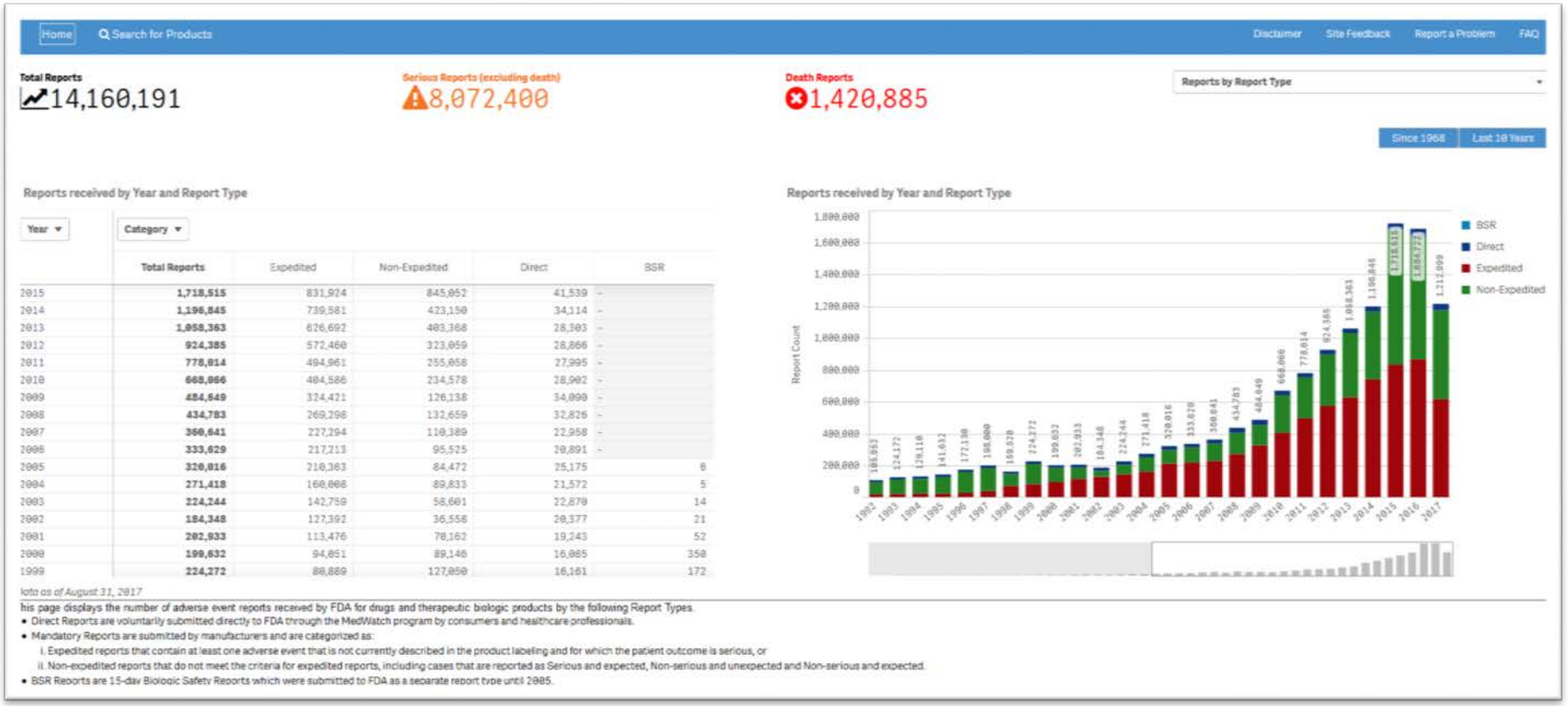
  - ii. Non-expedited reports that do not meet the criteria for expedited reports, including cases that are reported as Serious and expected, Non-serious and unexpected and Non-serious and expected.
- BSR Reports are 15-day Biologic Safety Reports which were submitted to FDA as a separate report type until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

Describes the details of data displayed on the page

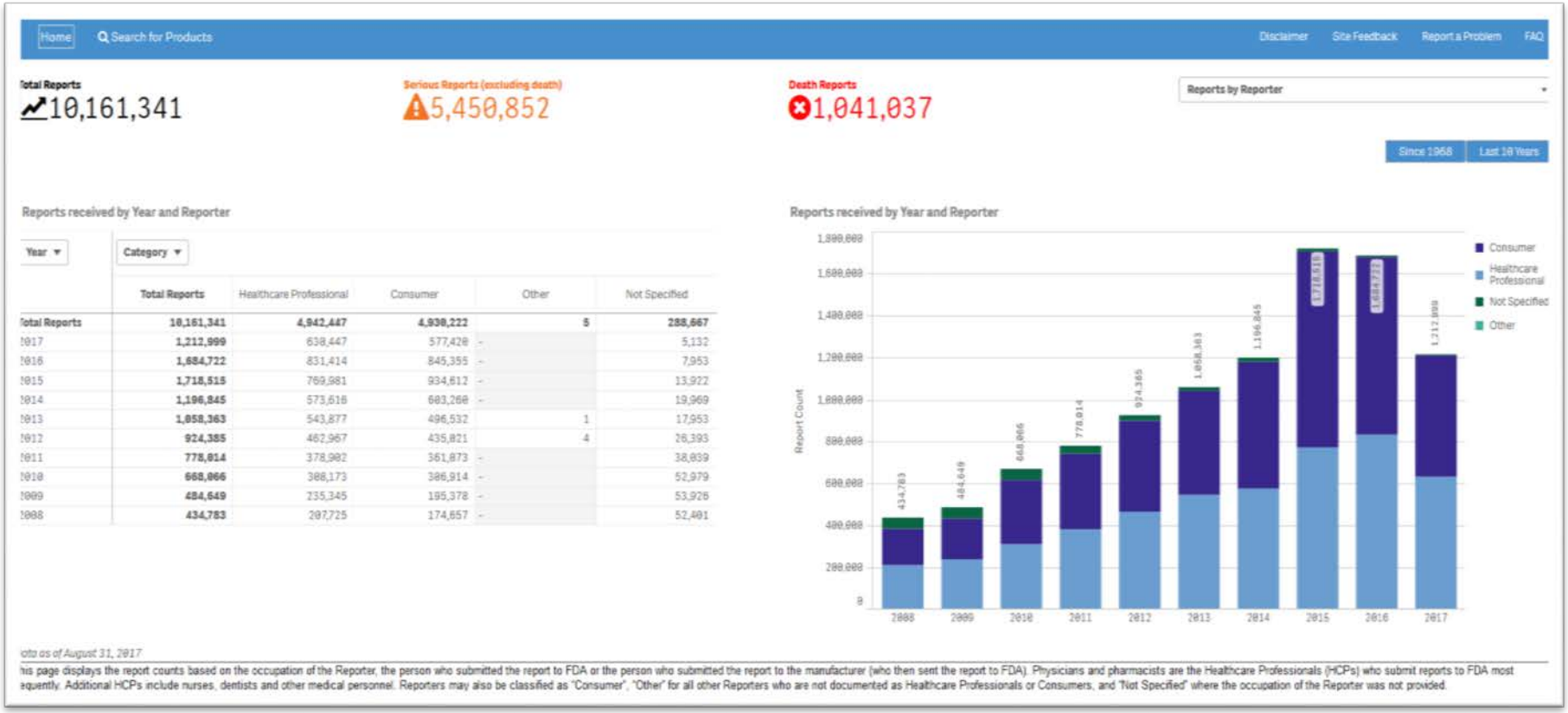
MAIN DASHBOARD
REPORTS BY REPORT TYPE

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



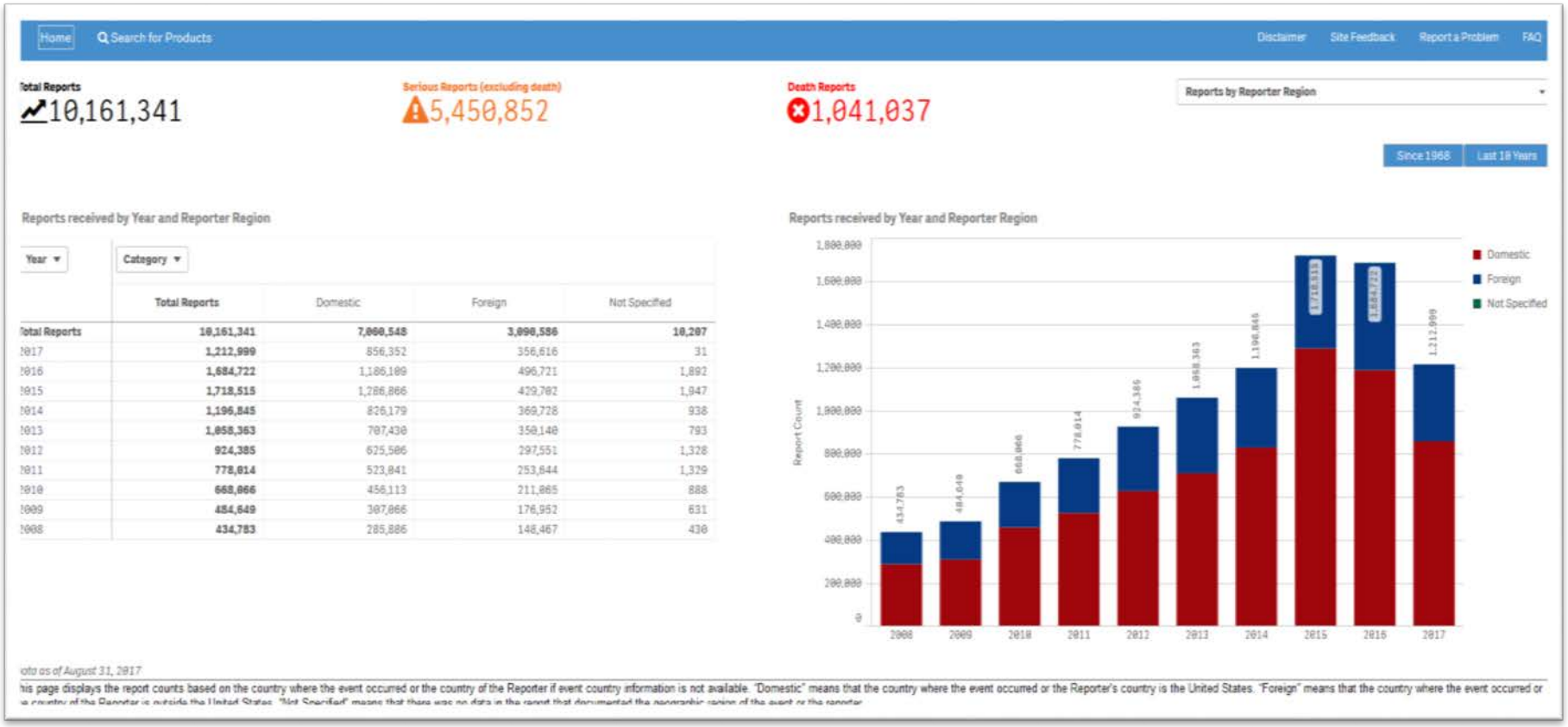
MAIN DASHBOARD
REPORTS BY REPORTER

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

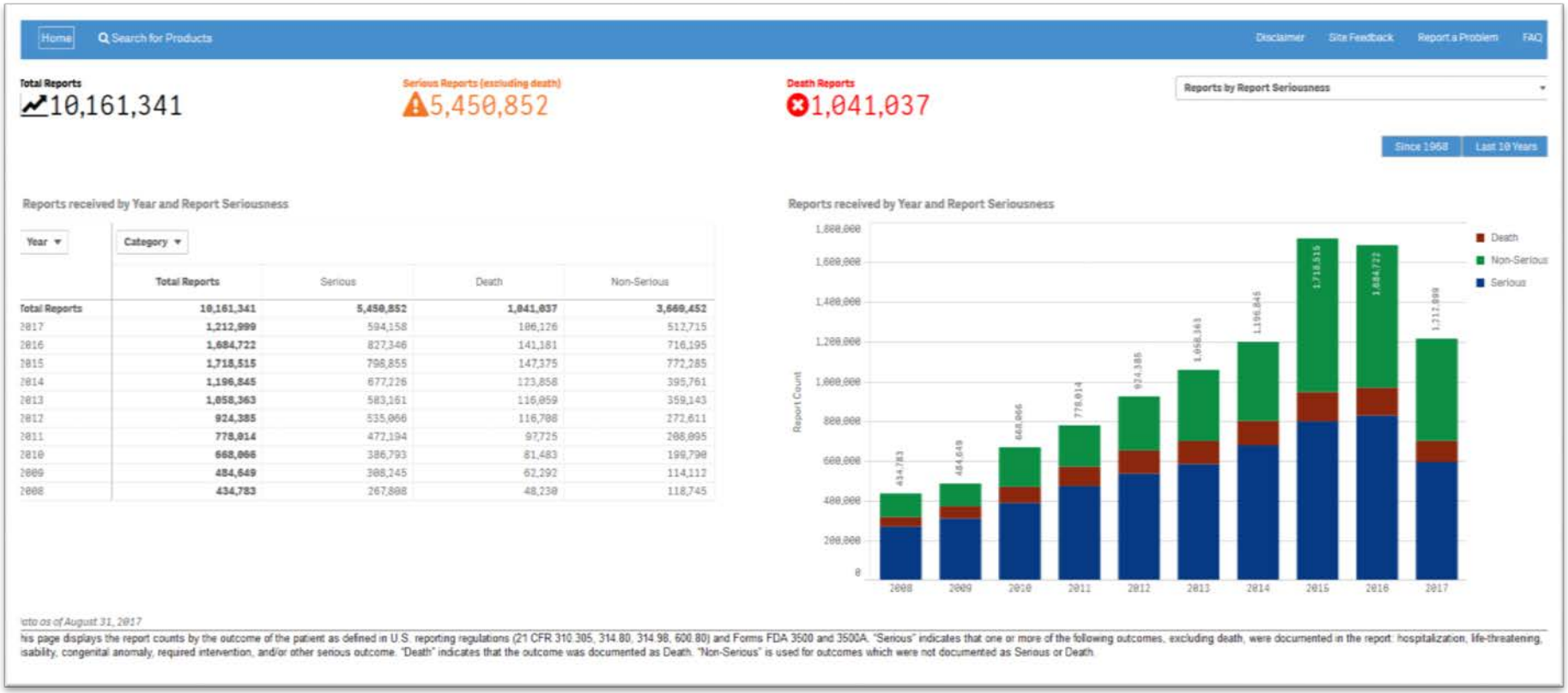
Displays the number of adverse event reports received by FDA for drugs and therapeutic biologic based on the country where the event occurred.



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

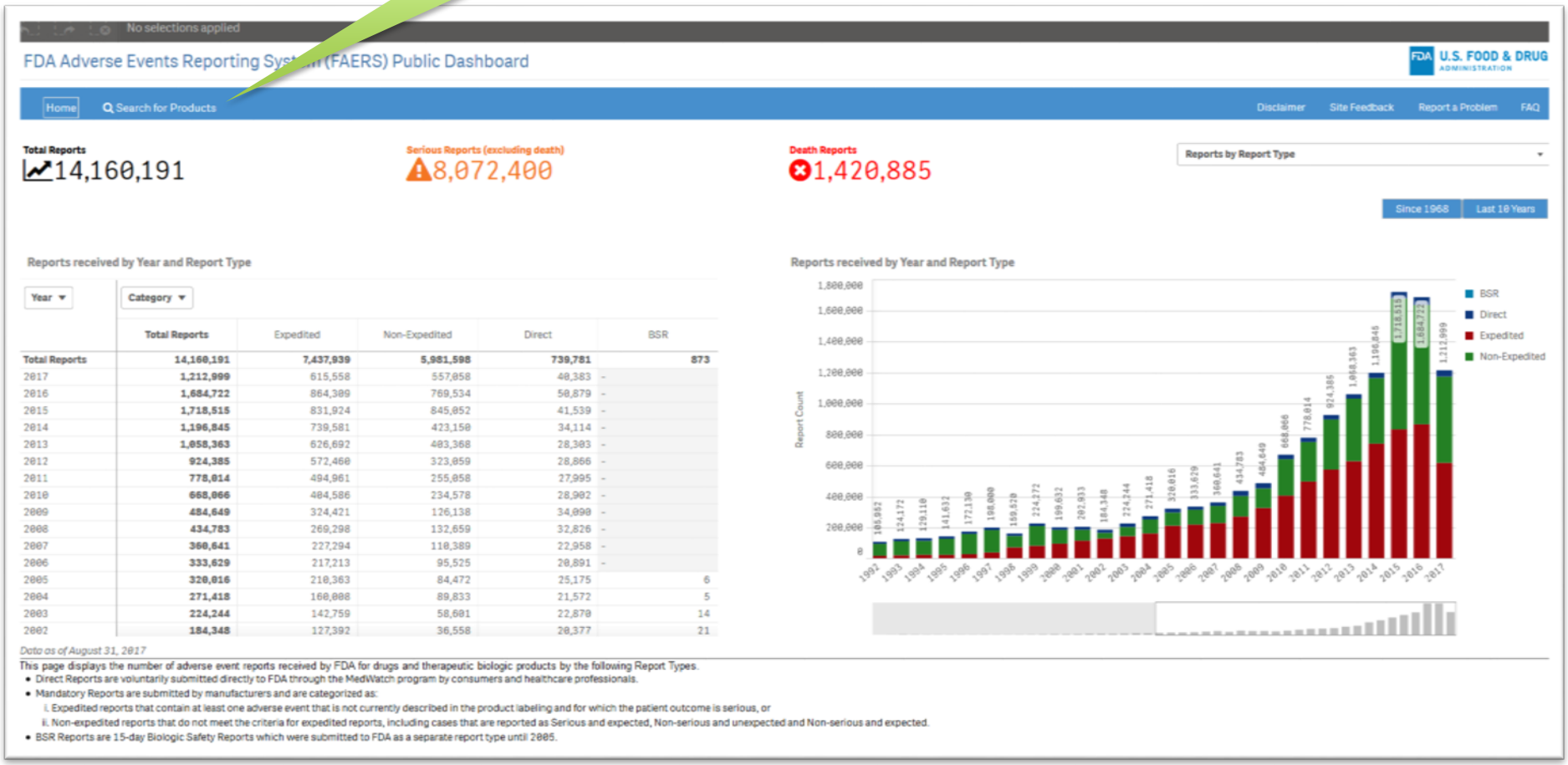
The main dashboard page displays report counts on which of the following criteria

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

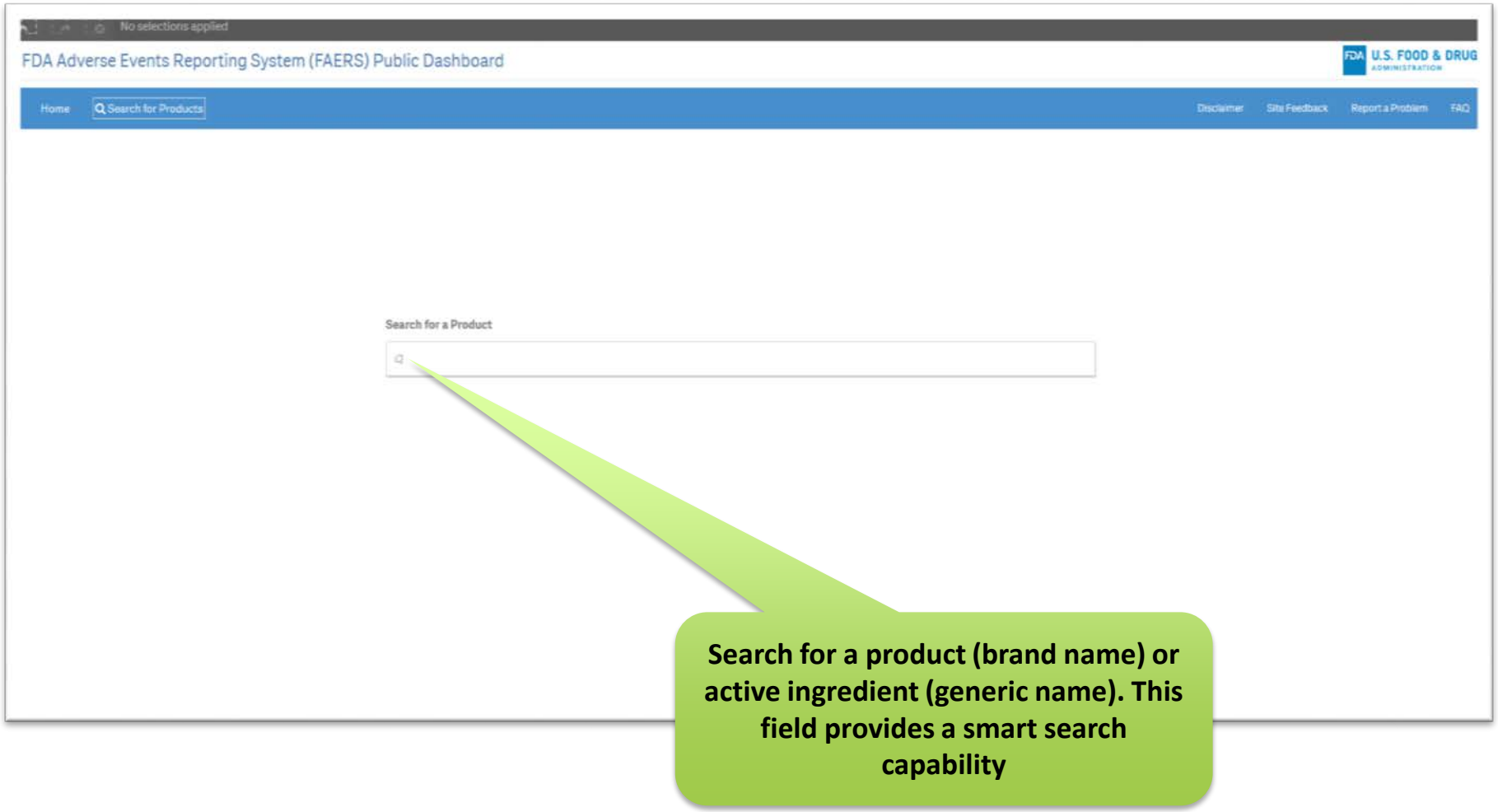
SEARCH FOR PRODUCTS

SEARCH FOR PRODUCTS

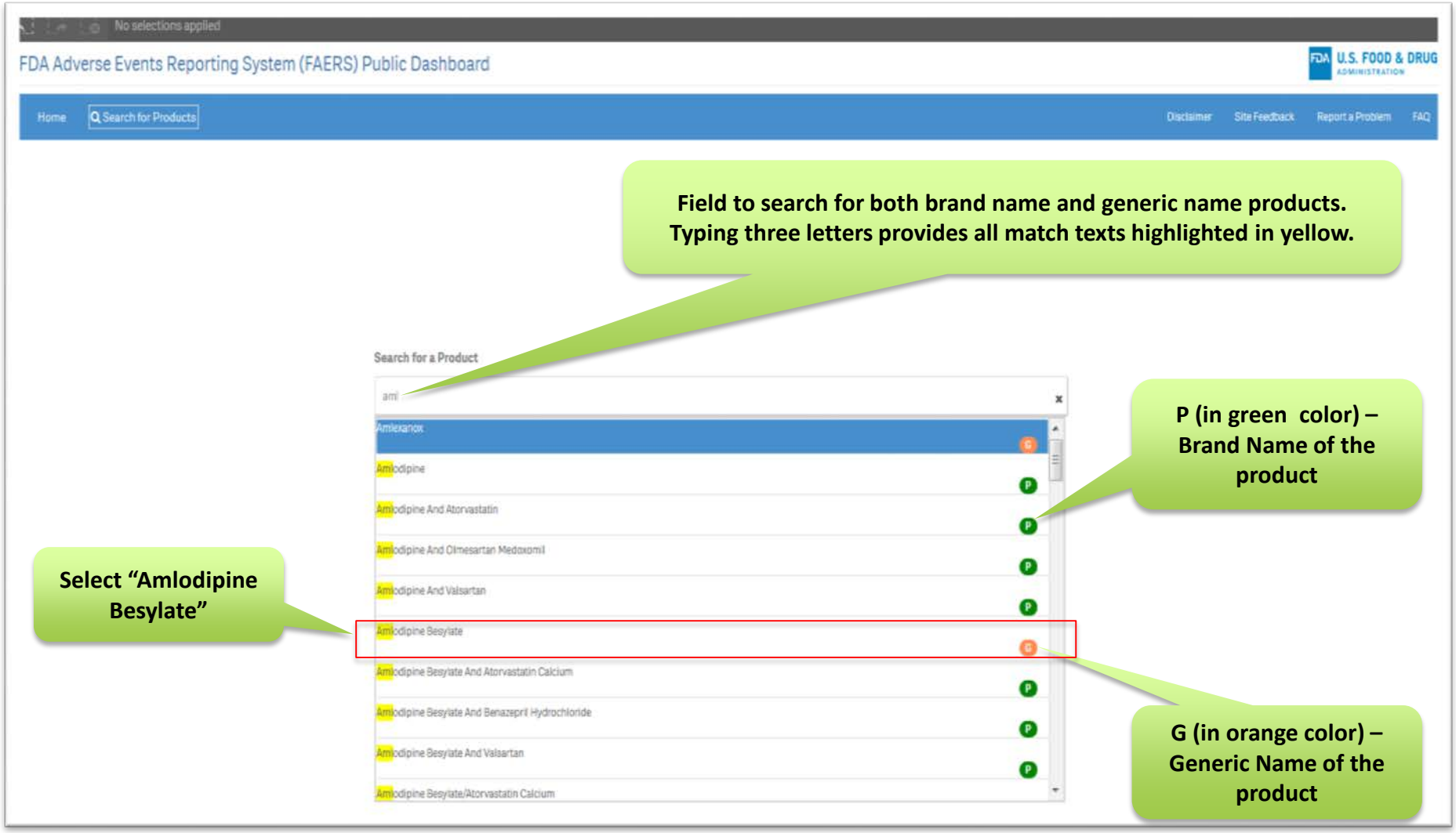
Search for products



SEARCH FOR PRODUCTS



SEARCH FOR PRODUCTS



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

DEMOGRAPHICS

Filters applied for years

Drag the mouse to select years or by individual clicks

Search Term Amlodipine Besyl... | Received Year 2017

FDA Adverse Events Reporting System (FAERS) Public Dashboard

U.S. FOOD & DRUG ADMINISTRATION

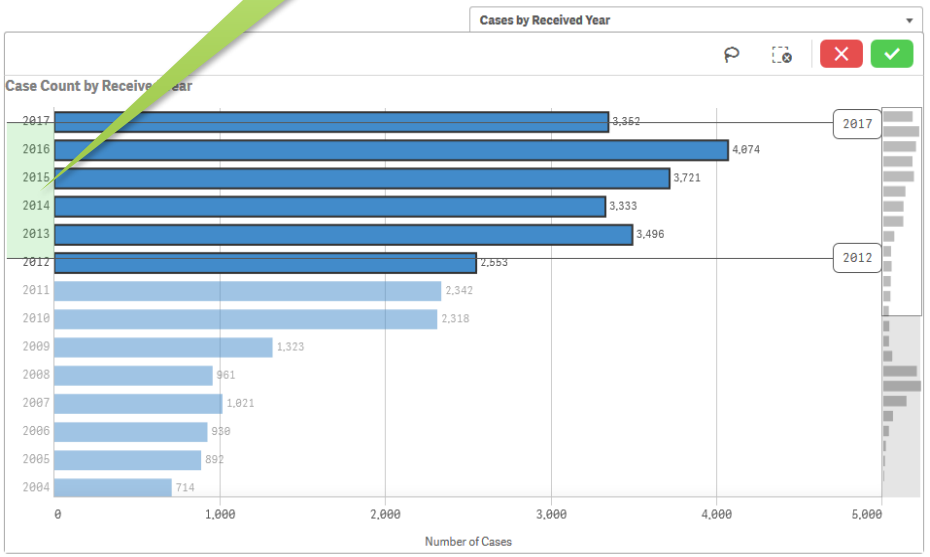
Home | Demographics | Reaction Group | Reaction | Listing of Cases | Disclaimer | Site Feedback | Report a Problem | Amlodipine Besylate

AMLODIPINE BESYLATE

Total Cases 3,352 | Serious Cases (in...aths) 2,76 | 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%**



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

Search Term: Amlodipine Besyl... | Received Year: 6 of 50

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

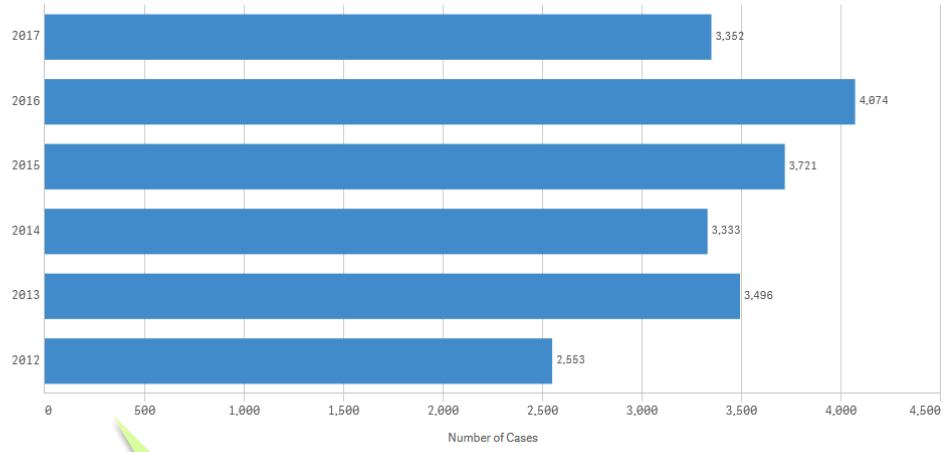
Death Cases: 3,146

Cases by 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%**

Case Count by Received Year



Data as of Augus

This page displa er 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

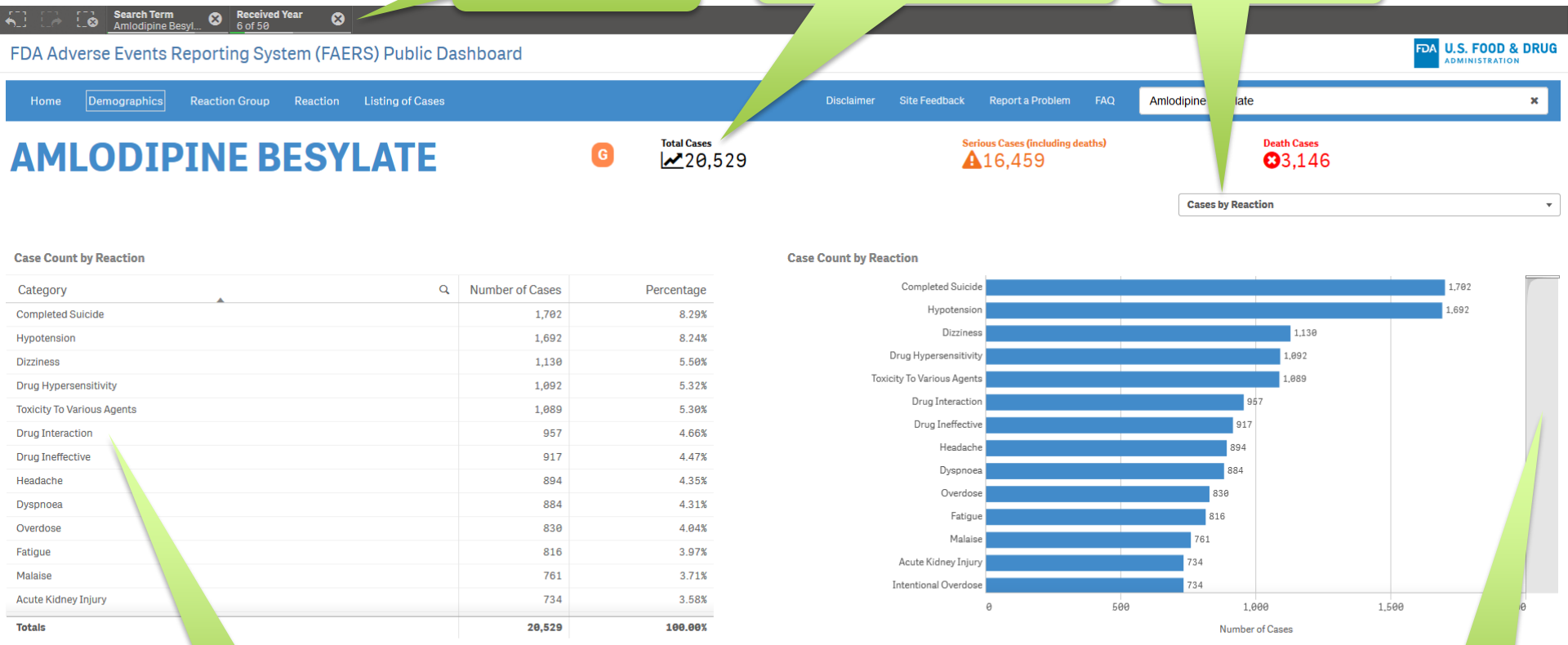
Case by years - graphical view

DEMOGRAPHICS

Years filter applied from 2012 to 2017

Total number of cases for the 2012 to 2017

Cases by Reactions



Reactions listed in descending order

Scrollbar to view all reactions

DEMOGRAPHICS

Years filter applied from 2012 to 2017

Total number of cases for the 2012 to 2017

Cases by Age Group

Search Term: Amlodipine Besyl... | Received Year: 6 of 50

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 B...e

AMLODIPINE BESYLATE

Total Cases: 20,529

Serious Cases (including deaths): 16,459

Death Cases: 3,146

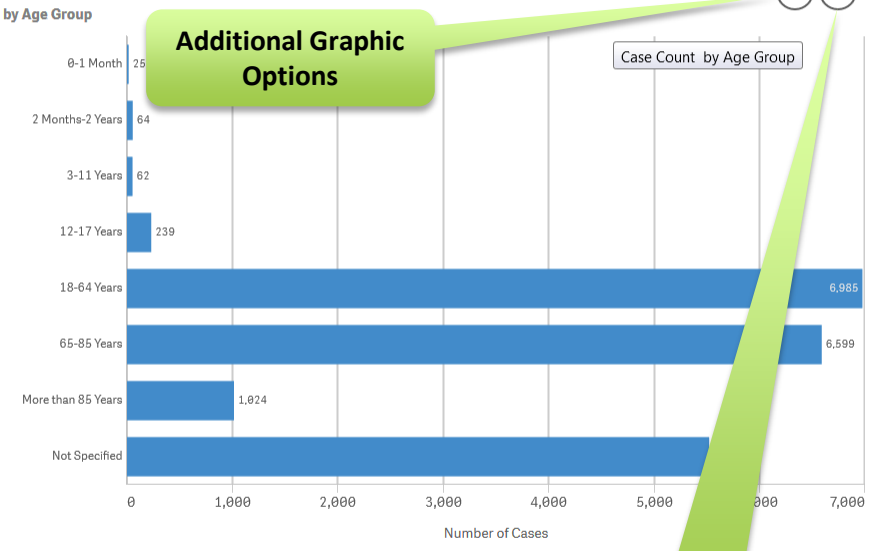
Cases by Age Group

Case Count 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%**

Case Count by Age Group

Additional Graphic Options



Click to expand the view

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.

DEMOGRAPHICS

Years filter applied from 2012 to 2017

Total number of cases for the 2012 to 2017

Cases by Sex

Search Term: Amlodipine Besyl... | Received Year: 6 of 50

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 ylate

AMLODIPINE BESYLATE

Total Cases: 20,529

Serious Cases (including deaths): 16,459

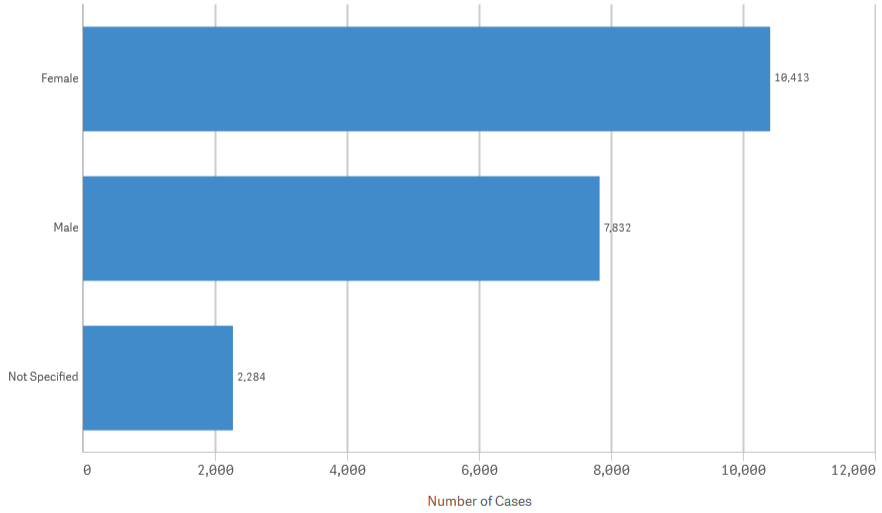
Death Cases: 3,146

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

Search Term: Amlodipine Besyl... | Received Year: 6 of 50

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 ate

AMLODIPINE BESYLATE

Total Cases: 20,529

Serious Cases (including deaths): 16,459

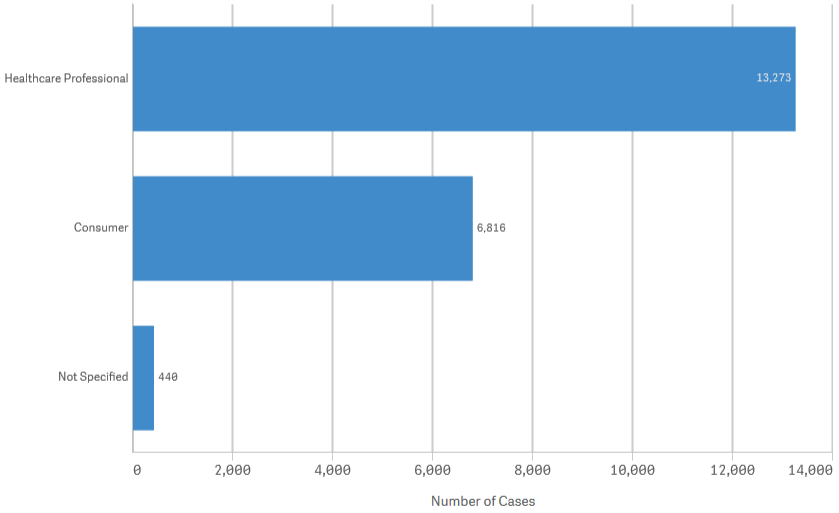
Death Cases: 3,146

Cases by Reporter Type

Case Count by Reporter

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



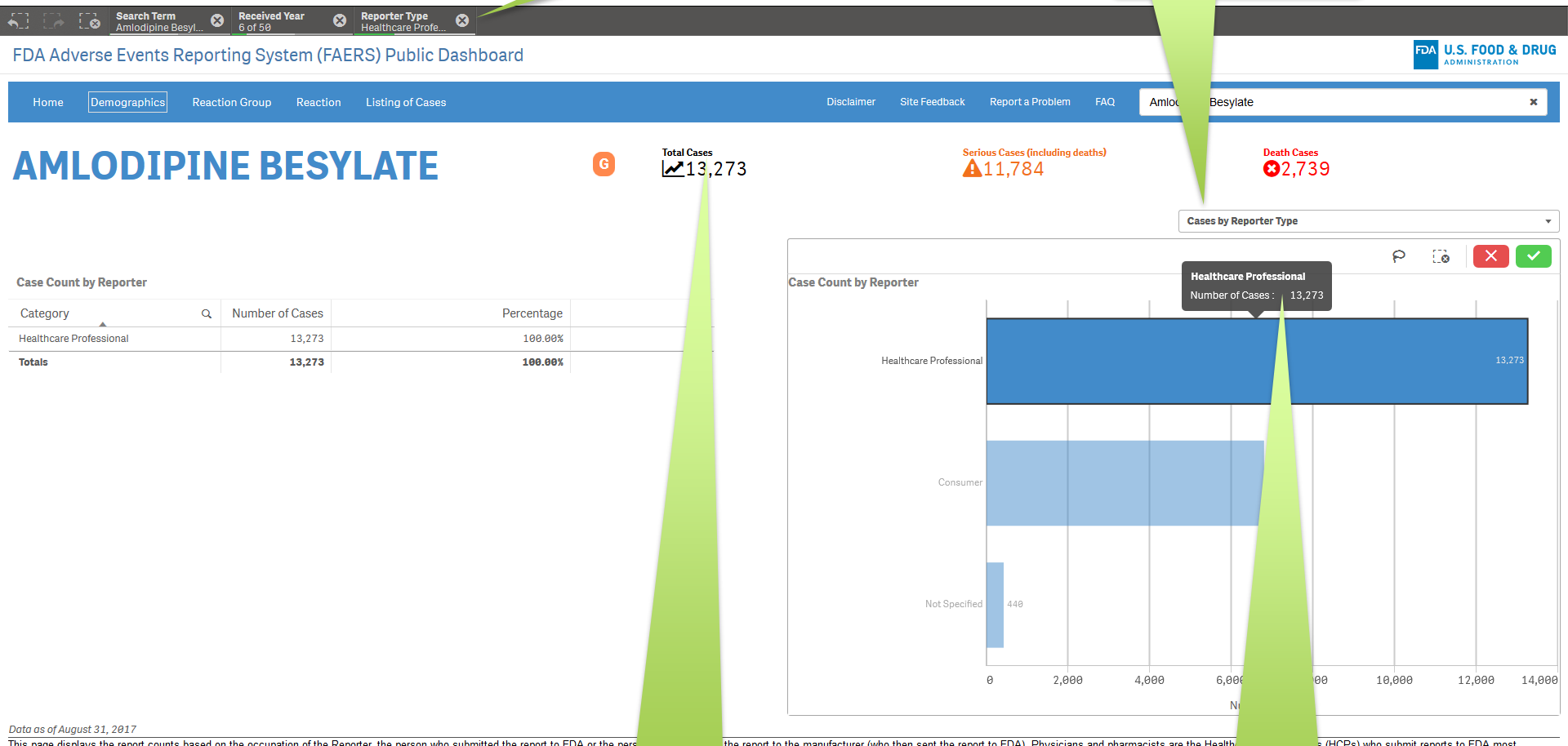
Data as of August 31, 2017

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

Search Term: Amlodipine Besyl... | Received Year: 6 of 50 | Reporter Type: Healthcare Profe... | Age Group: 2 of 8

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AMLODIPINE BESYLATE

Total Cases: 5,325

Serious Cases (including deaths): 4,952

Death Cases: 1,554

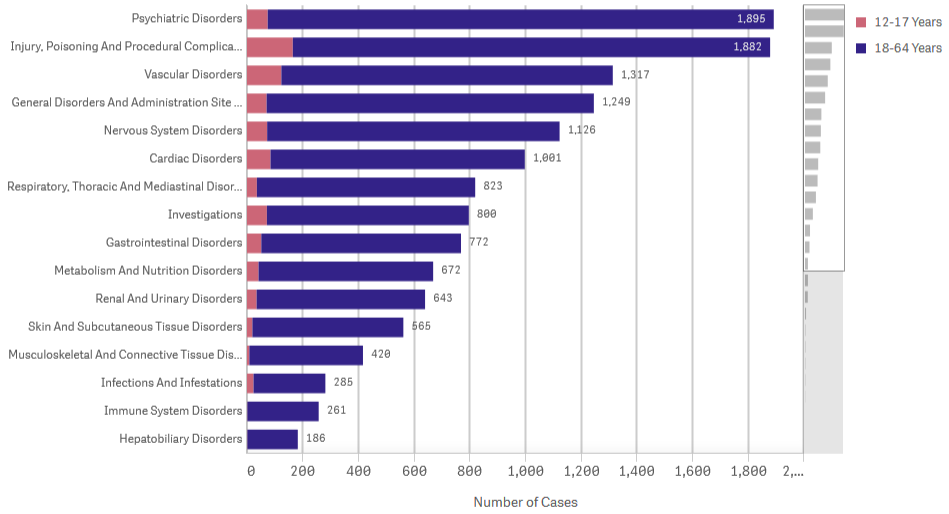
Cases by Age Group

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	**420**	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

Reaction Groups & Age Group



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 Sex

Search Term: Amlodipine Besyl... | Received Year: 6 of 50 | Reporter Type: Healthcare Profe... | Age Group: 2 of 8

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AMLODIPINE BESYLATE

Total Cases: 5,325

Serious Cases (including deaths): 4,952

Death Cases: 1,554

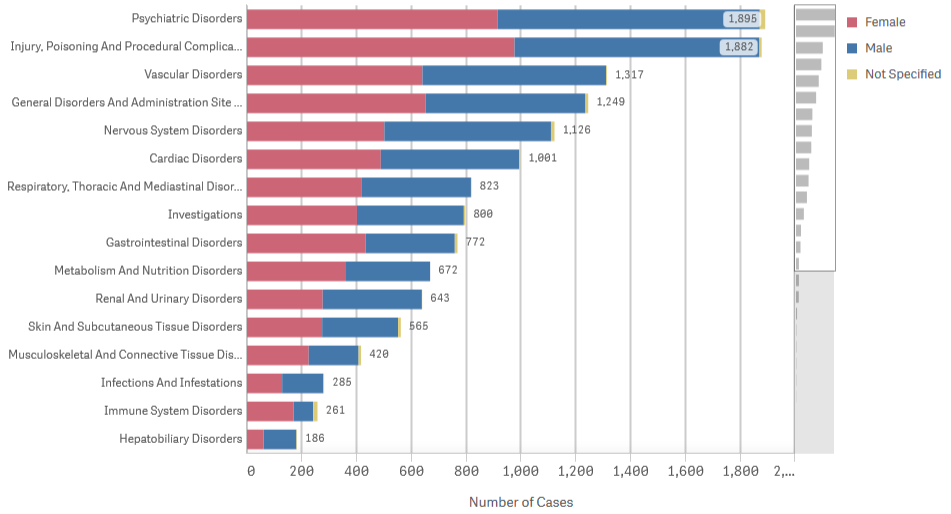
Cases by Sex

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



Data as of August 31, 2017

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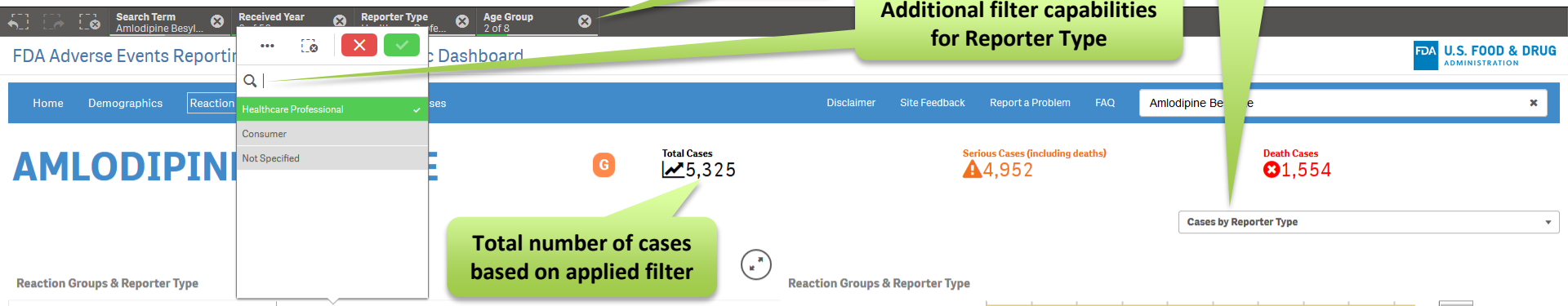
REACTION GROUP

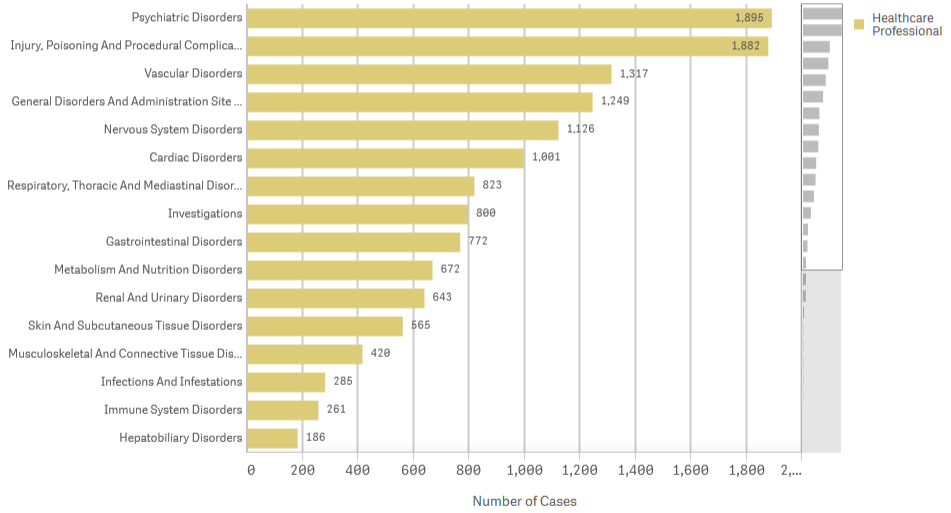


Reaction Groups & Reporter Type

Reaction Group ▾ | Select category ▾

	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	**420**	420
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



Data as of August 31, 2017

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REACTION GROUP

Age group filter applied

Total number of cases based on applied filter

Cases by Reporter Region

Search Term: Amlodipine Besyl... | Received Year: 6 of 50 | Reporter Type: Healthcare Profe... | Age Group: 2 of 8

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AMLODIPINE BESYLATE

Total Cases: 5,325

Serious Cases (including deaths): 4,952

Death Cases: 1,554

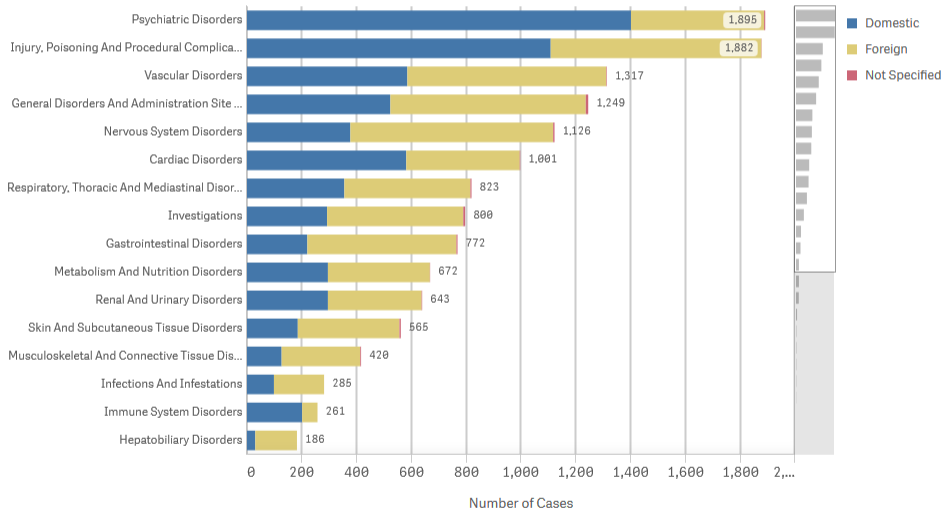
Cases by Reporter Region

Reaction Groups & Reporter Region

Reaction Group | Select category

	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



Data as of August 31, 2017

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QUESTIONS 9

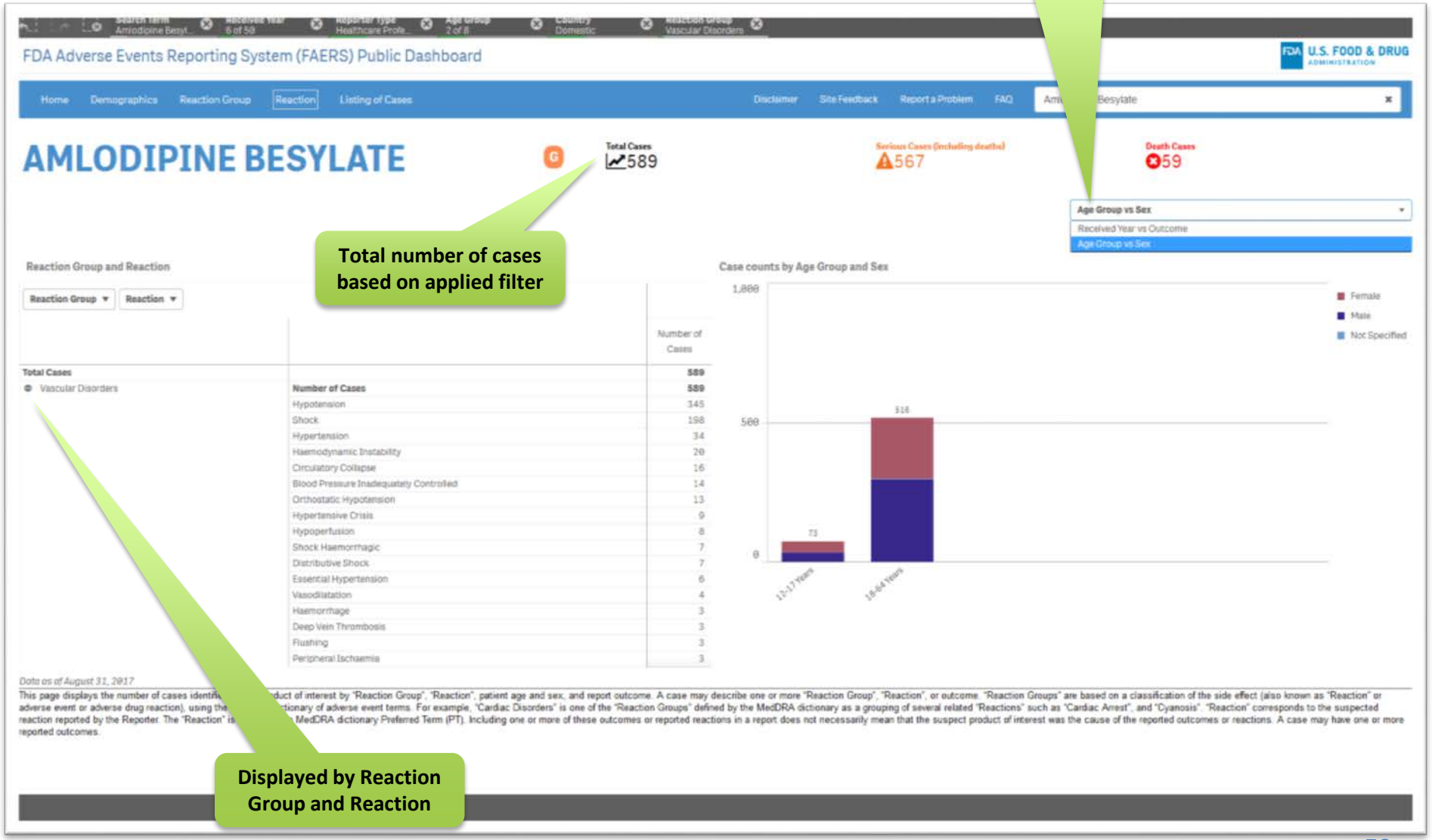
Rebecca has extended her search and now she wants to view the information for only domestic cases and under nervous system disorders.
Which selections steps are the best to get quickly to results?

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
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Total Cases
589
Serious Cases (including deaths)
567
Death Cases
59
Age Group vs Sex
Received Year vs Outcome
Age Group vs Sex
Total number of cases based on applied filter
Reaction Group and Reaction
Reaction Group
Reaction
Number of Cases
Total Cases 589
Vascular Disorders
Number of Cases 589
Hypotension 345
Shock 198
Hypertension 34
Haemodynamic Instability 20
Circulatory Collapse 16
Blood Pressure Inadequately Controlled 14
Orthostatic Hypotension 13
Hypertensive Crisis 9
Hypoperfusion 8
Shock Haemorrhagic 7
Distributive Shock 7
Essential Hypertension 6
Vasodilatation 4
Haemorrhage 3
Deep Vein Thrombosis 3
Flushing 3
Peripheral Ischaemia 3
Case counts by Age Group and Sex
1,000
500
0
516
73
Female
Male
Not Specified
12-17 Years
18-64 Years
Displayed by Reaction Group and Reaction

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

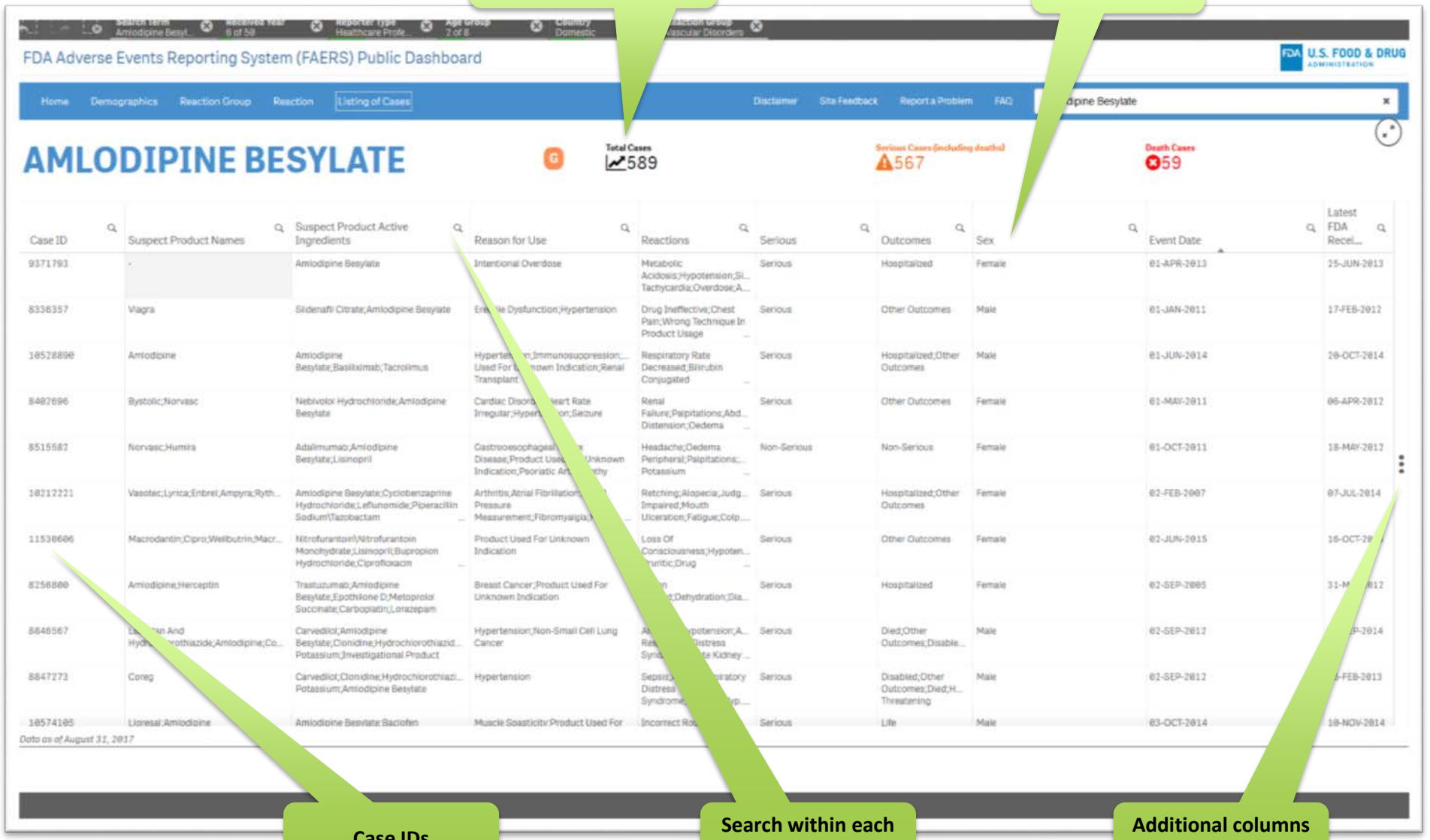
QUESTIONS 11

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.

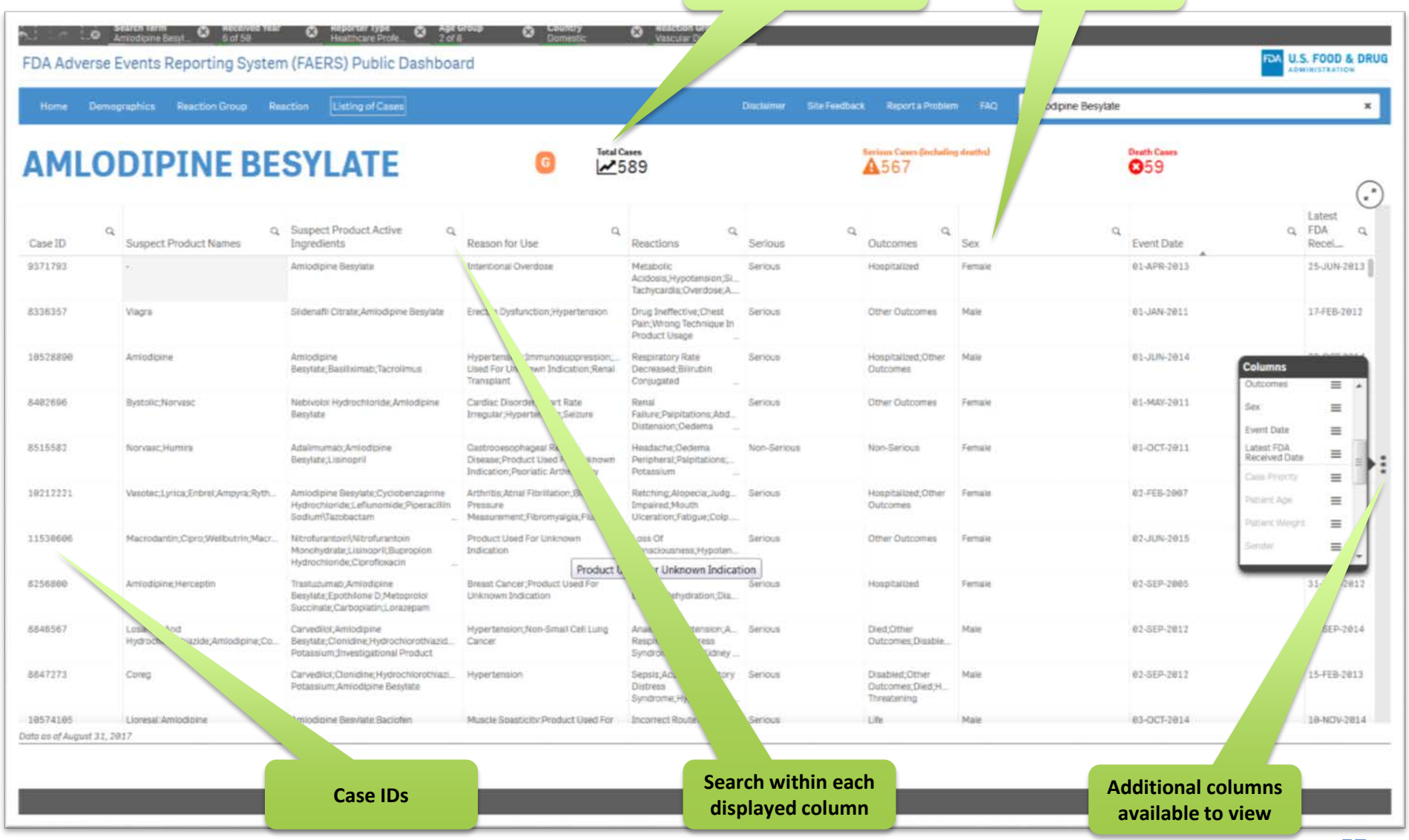
a. “Amlodipine Besylate” caused serious “Deep Vein Thrombosis” reaction
b. “Amlodipine Besylate” did not cause serious “Deep Vein Thrombosis” reaction
c. “Amlodipine Besylate” may have caused “Deep Vein Thrombosis” reaction
d. Not enough information to determine the causal relation

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.

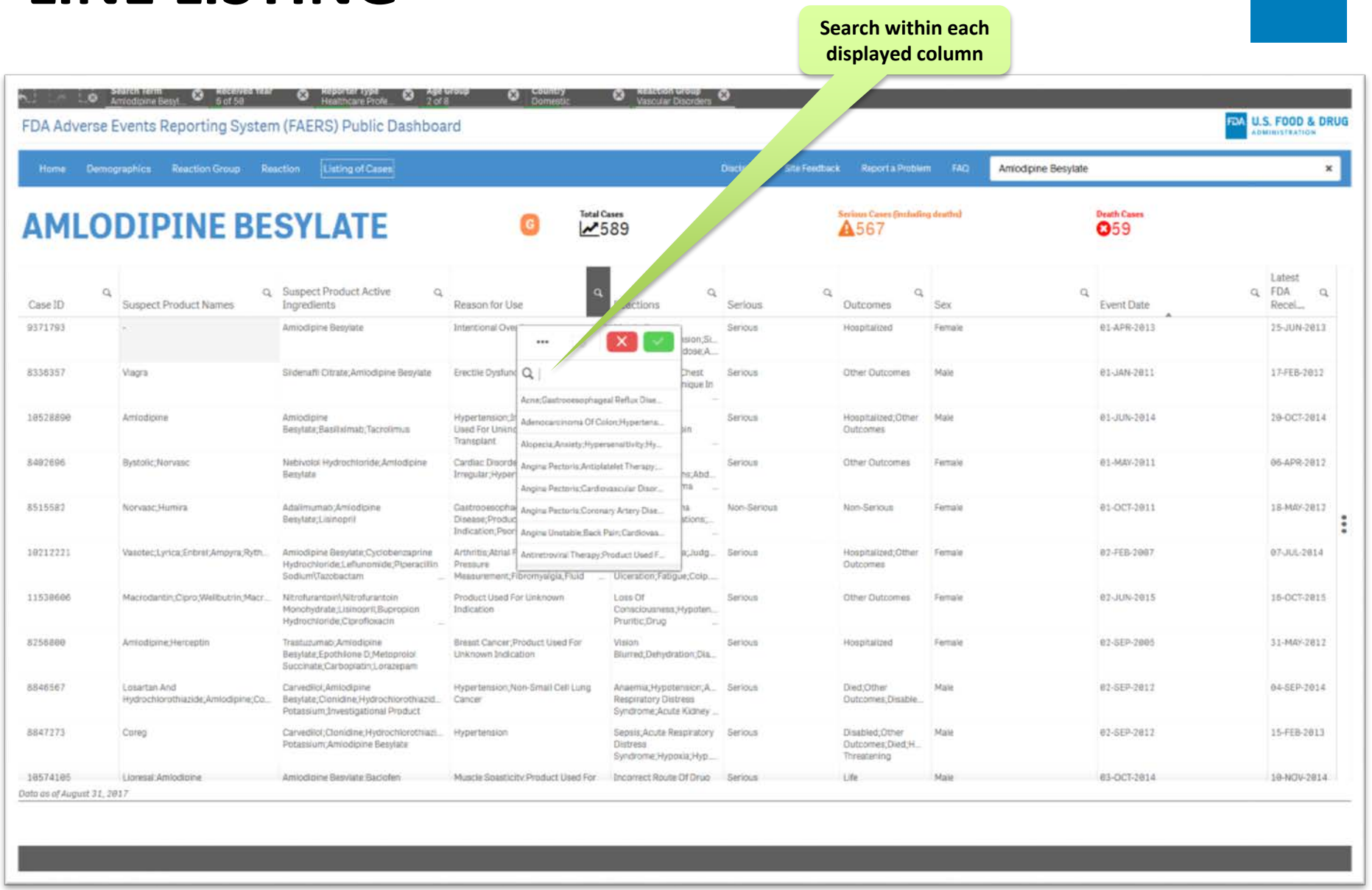
LINE LISTING



LINE LISTING



LINE LISTING



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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