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EudraVigilance - European database of suspected adverse reactions related to medicines: User Manual for online access via the adrreports.eu portal

Version 2.0

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Contents

Contents 2

Overview 3

1. Background Information 4

2. Disclaimer 4

3. Data elements for the aggregated web (dashboard) reports 5

4. Additional details on data elements for the aggregated web (dashboard) reports 7

4.1. Rules for when an individual case has more than one reporter 7

4.2. Rules for when an individual case has more than one suspected adverse reaction with different outcome 7

5. Layout 8

5.1. Tab 1 - Number of individual cases 8

5.2. Tab 2 - Number of individual cases received over time 8

5.3. Tab 3 - Number of individual cases by EEA countries 9

5.4. Tab 4 - Number of individual cases by Reaction Group 9

5.5. Tab 5 - Number of individual cases for a selected Reaction Group 10

5.6. Tab 6 - Number of individual cases for a selected Reaction 11

5.7. Tab 7 – Line Listing 11

6. Interpretation of web reports 14

7. Web report functionalities 15

7.1. General Navigation 15

7.1.1. Graph/Grid view 16

7.1.2. Legend 17

7.2. Navigation in Tab 2 – Number of individual cases received over time 17

7.3. Navigation in Tab 4 – Number of individual cases by reaction groups 18

7.4. Navigation in Tab 5 – Number of individual cases for a selected reaction group 18

7.5. Navigation in Tab 6 – Number of individual cases for a selected adverse reaction 18

7.6. Navigation in Tab 7 – Line Listing 19

7.6.1. Filtering the Line Listing 19

7.6.2. Line Listing and ICSR Form functionality 21

8. List of acronyms used in the document 23

9. Supporting documents 23

Overview

This manual provides instructions on how to use the adrreports.eu portal to obtain access in EudraVigilance to reports of suspected adverse reactions (also referred to as undesirable effects or side effects) related to medicines. The access to information on suspected adverse reactions related to medicines is defined in the EudraVigilance Access Policy.

By means of the adrreports.eu portal, web reports can be generated that provide information on suspected adverse reactions related to medicines authorised in the European Economic Area (EEA).

Details of the web reports are described in this manual. This includes explanations on the available browsing/query functionalities, the layout of the reports and the data elements presented for Individual Case Safety Reports (ICSRs). Guidance on the interpretation of spontaneous case reports of suspected adverse reactions to medicines is provided here.

1. Background Information

The adrreports.eu portal provides public access to reports of suspected side effects submitted to the EudraVigilance system by national medicines regulatory authorities and pharmaceutical companies that hold marketing authorisations for medicines in the European Economic Area (EEA).

The European Medicines Agency (EMA) plays a key role in the safety monitoring of medicines in the European Union (EU) - this is known as pharmacovigilance. The Agency's main role in this area is to support the coordination of the European pharmacovigilance system and to provide advice on the safe and effective use of medicines. As part of this responsibility, the Agency is responsible for the development, maintenance and co-ordination of EudraVigilance, a system for reporting suspected cases of adverse reactions to a medicine. For more information please visit the EMA website.

Data in EudraVigilance is submitted electronically by national medicines regulatory authorities and by pharmaceutical companies that hold the marketing authorisation for medicines. EudraVigilance data are published in the European database of suspected adverse drug reaction reports, the adrreports.eu portal, in 26 languages. This portal allows users to view the total number of individual suspected side effect reports (also known as Individual Case Safety Reports, or ICSRs) submitted to EudraVigilance for medicines authorised in the EEA. The EMA publishes the data available on the adrreports.eu portal so that its stakeholders, including the general public, can access information that European regulatory authorities can use to review the safety of a medicine or active substance.

The data available in the portal is **based on adverse reactions reported spontaneously by patients, healthcare professionals or other sources**, which are then submitted electronically to EudraVigilance in the form of an ICSR by national medicines regulatory authorities or pharmaceutical companies.

The adrreports.eu portal grants access to aggregated data outputs based on predefined queries. These are made available in the form of web reports that consist of a number of tabs, each of which allows users to query, filter and access the data in a different way. In addition, access to line listing of individual cases and individual case report forms is provided in compliance with EU personal data protection law.

2. Disclaimer

The Information on suspected adverse reactions that can be accessed via the adrreports.eu portal should not be interpreted as meaning that the medicine or the active substance causes the observed effect or is unsafe to use. Information on the portal relates to suspected side effects, so medical events that have been observed following the use of a medicine, but which are not necessarily related to or caused by the medicine. The number of suspected adverse reactions in EudraVigilance should not serve as a basis for determining the likelihood of an adverse reaction occurring.

The ICSRs in EudraVigilance do not represent all available information concerning the benefits and risks of a medicine and should not be used in isolation by healthcare professionals to make decisions regarding a patient's treatment regimen; other sources of information, including the product/prescribing information, should also be consulted.

3. Data elements for the aggregated web (dashboard) reports

Before an ICSR is submitted to EudraVigilance, the reporter completes the applicable data elements and provides information on the suspected adverse reaction(s) (also known as side effect or undesirable effect) that have been observed following the use of one or more medicines. These suspected side effects are not necessarily related to or caused by the medicine (please see Guidance on the interpretation of spontaneous case reports of suspected adverse reactions to medicines).

The web reports that can be accessed via the adrreports.eu portal provide different views of data on ICSRs, which form part of each individual case submitted to EudraVigilance. The data elements available to users of the portal are determined by the EudraVigilance Access Policy.

For the aggregated web (dashboard) reports the following applies:

- **Age Group** and **Sex** provide information on the individual, who experienced the suspected undesirable effect.
- **Report Type** provides information on the classification of a report by the sender (e.g. spontaneous report).
- **Seriousness** provides information on the suspected undesirable effect; it can be classified as 'serious' if it corresponds to a medical occurrence that results in death, is life-threatening, requires inpatient hospitalisation, results in another medically important condition, or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly/birth defect. It can also refer to other important medical events that might not be immediately life threatening or result in death or hospitalisation but might jeopardise the patient or might require intervention (treatment) to prevent one of the other outcomes listed above. Examples of such events are allergic bronchospasm (a serious problem with breathing) requiring treatment in an emergency room or at home as well as seizures/convulsions and serious blood dyscrasias (blood disorders) that do not result in hospitalisation.
- **Geographic Origin** provides information on the location of the reporter.
- **Reporter Group** provides information on the qualification of the reporter.
- **Outcome** provides information on the last reported status of the suspected undesirable effect.
- **Reported suspected reaction** provides information on the undesirable effect(s) experienced by a patient according to the reporter.

The table below presents the data elements included in the web reports and possible values.

Data element	Possible Values
Age group (mapped against "Age at Time of Onset of Reaction/Event", based on the reported patient age or calculated based on difference between "Date of Birth" and "First Reaction Start Date" (if available in a valid date format dd/mm/yyyy)	Not Specified
	0-1 Month
	2 Months - 2 Years
	3-11 Years
	12-17 Years
	18-64 Years
	65-85 Years
	More than 85 Years
Sex	Female

Data element	Possible Values
	Male
	Not Specified
Report Type	Spontaneous
Seriousness	Not Specified
	Serious
	Non-Serious
Geographic Origin	European Economic Area (EEA)
	Non-European Economic Area (Non-EEA)
	Not Specified
Reporter Group	Healthcare Professional (Physician, Pharmacist or Other Health Professional)
	Non-Healthcare Professional (Lawyer, Consumer or Other non-Health Professional)
	Not Specified
Outcome	Recovered/resolved
	Recovering/resolving
	Not recovered/not resolved
	Recovered/resolved with sequelae
	Fatal
	Unknown
	Not specified
Reported Suspected Reaction	Any undesirable effect (suspected adverse reaction) reported by the reporter Undesirable effect terms are coded in line with a dictionary of medical terms used to classify clinical information
Reaction Groups	Any undesirable effect group based on the classification reported by the reporter Undesirable effect terms come from the dictionary of medical terms used to classify clinical information and are categorised into groups based on the clinical signification
Number of individual cases	Running total count of individual cases submitted to EudraVigilance

The **Reported Suspected Reaction** and **Reaction Groups** for a report are derived from the dictionary of medical terms used to classify clinical information. The dictionary used is the Medical Dictionary for Regulatory Activities (MedDRA®).

The **Reported Suspected Reaction** corresponds to the MedDRA reaction 'Preferred Term (PT)' and the **Reaction Groups** correspond to the MedDRA Reaction 'System Organ Class (SOC)'.

The table provides examples of the MedDRA classification:

Suspected Reported Reaction (Preferred Term in MedDRA)	Reaction Group (System Organ Class in MedDRA)
Headache	Nervous system disorders
Ear infection	Infections and infestations

For further information about the dictionary, please consult the adrreports.eu FAQ page 'What is the Medical Dictionary for Regulatory Activities (MedDRA®)?'.

4. Additional details on data elements for the aggregated web (dashboard) reports

An individual case can only have one value for the data elements **Age Group**, **Sex, Report Type** and **Geographic Origin**; for the data elements **Reporter Group, Seriousness** and **Outcome**, more than one value can be available.

This is because an individual case concerns one individual patient, therefore the **Age Group, Sex** and **Geographic Origin** can only be characterised by one value.

However, an individual case may have been reported by a Consumer and a Physician, which belong to different **Reporter Groups**; the **Outcome** of a suspected undesirable effect might have been reported as 'recovering' at the time of the initial report and following an update it is now reported as 'unknown'.

To address these eventualities and prevent an over-counting of the number of individual cases in the web reports, the following rules are applied:

4.1. Rules for when an individual case has more than one reporter

If at least one of the reporters is indicated as being a 'Physician', 'Pharmacist' or 'Other Health Professional', the **Reporter Group** is defined as 'Healthcare Professional'. Otherwise, if the reporters are indicated as being a 'Lawyer' or 'Consumer or other non-Health Professional', the Reporter Group is defined as 'Non-Healthcare Professional'.

	Reporter(s)	Reporter Group
Individual case #1	Pharmacist	Healthcare Professional
Individual case #2	Physician; Lawyer or Consumer	Healthcare Professional
Individual case #3	Other non Health Professional	Non-Healthcare Professional

4.2. Rules for when an individual case has more than one suspected adverse reaction with different outcome

If at least one of the outcomes is fatal, the outcome for the individual case for the reported reaction is defined as 'Fatal'; if none of the outcomes is fatal, the outcome for the individual case for the reported reaction is defined as 'Unknown'.

	Reported Suspected Adverse Reactions and Outcome(s)	Outcome in web report
Individual case #4	The same reaction is not reported twice: Reaction **A** -> Recovered/resolved Reaction **B** -> Not Specified	Reaction **A** -> Recovered/resolved Reaction **B** -> Not Specified

	Reported Suspected Adverse Reactions and Outcome(s)	Outcome in web report
Individual case #5	The same reaction is reported twice: Reaction **C** -> Recovering/resolving Reaction **C** -> Fatal	Reaction **C** -> Fatal
Individual case #6	The same reaction is reported twice: Reaction **D** -> Recovered/resolved Reaction **D** -> Recovered/resolved with sequelae	Reaction **D** -> Unknown

5. Layout

The web report is composed of 7 tabs.

5.1. Tab 1 - Number of individual cases

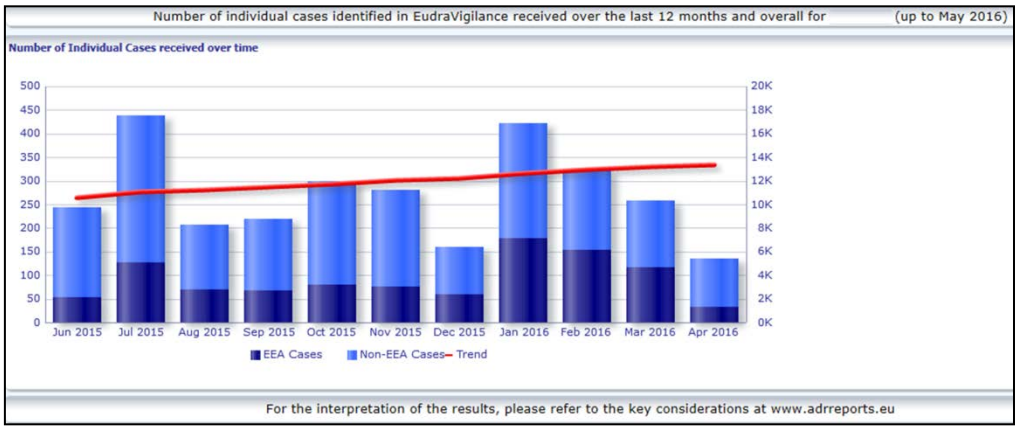
The tab provides the **running total of individual cases** identified in EudraVigilance up to the end of the previous month.

The tab presents the information on the number of individual cases by **Age Group**, **Sex** and **Geographic Origin**.

5.2. Tab 2 - Number of individual cases received over time

The tab displays the number of individual cases received over the **last 12 months** split by **geographic origin** i.e. cases arising in EEA countries relative to those arising outside of the EEA.

The graph on this tab also contains a trend line to indicate the **total number of individual cases over time**.



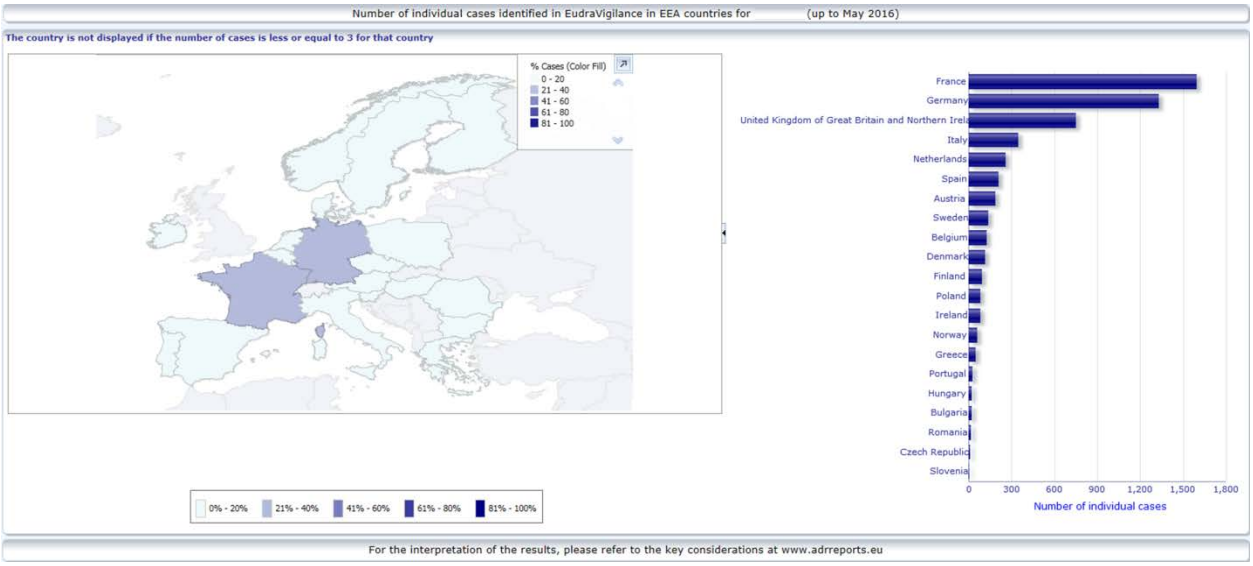
Note that the legend for the total number of cases over time is express in K, i.e. 4K means 4000.

5.3. Tab 3 - Number of individual cases by EEA countries

The tab displays the number of individual cases in **EEA countries for the selected medicinal product / substance.**

The **map view displays the percentage of total EEA cases** in each country.

The graph view displays the total number of individual cases in each country.



For data privacy reasons and to avoid the risk of patient/reporter re-identification, a threshold is applied if the number of individual cases available for a specific country is less or equal to 3. In this instance, the distinct country is not displayed in the graph.

A colour coding has been applied according to the percentage of cases in a country.

5.4. Tab 4 - Number of individual cases by Reaction Group

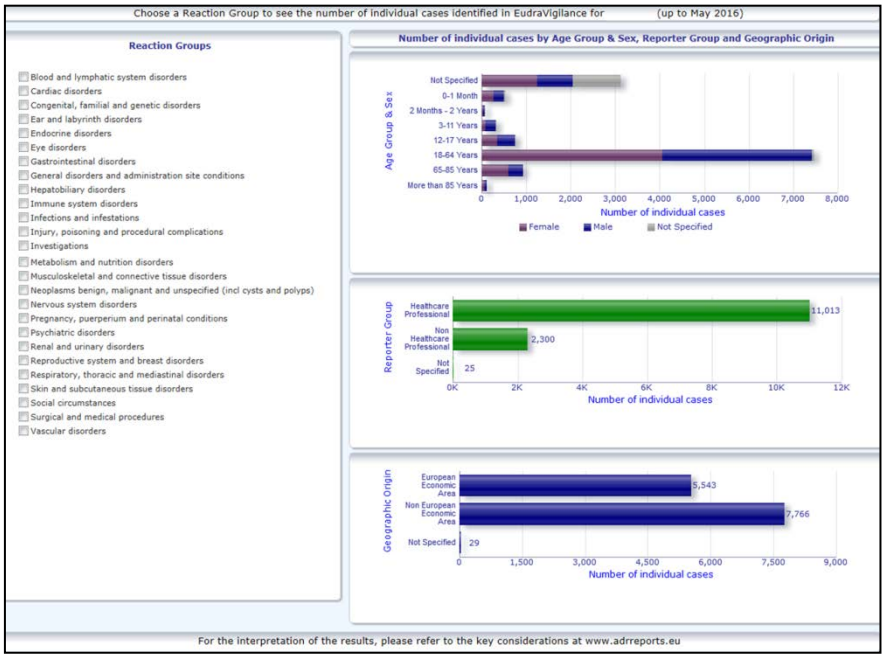
The tab displays a graph that visualises the number of individual cases by Reaction Group.

Five distinct views are available, allowing users to split the Reaction Group data on this tab by Age Group, Sex, Seriousness, **Reporter Group** and **Geographic Origin**.

5.5. Tab 5 - Number of individual cases for a selected Reaction Group

The tab displays the number of individual cases for a selected Reaction Group defined by the user.

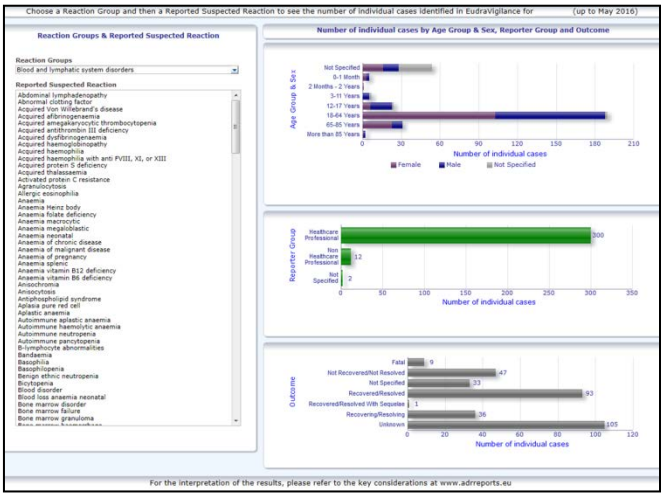
Three web reports for a selected Reaction Group are available; the first web report presents the data by **Age Group & Sex**, the second by **Reporter Group** and the third by **Geographic Origin**.



5.6. Tab 6 - Number of individual cases for a selected Reaction

This tab displays the number of individual cases for a selected Reaction which is defined by the user.

Three web reports for a selected Reaction are available: the first report presents the data by **Age Group & Sex**, the second by **Reporter Group** and the third by **Outcome**.



5.7. Tab 7 – Line Listing

The tab displays **the line listing of individual cases reported to EudraVigilance for a specified product or substance**. Data elements are displayed as per the level of access granted to the public in the EudraVigilance Access Policy.

The data elements listed below can be used to filter the line listing:

- Seriousness
- Geographic Origin
- Reporter Group
- Sex
- Age Group
- Reaction Groups
- Reporter Suspected Reaction
- Gateway Date

See **section 7.6.** for detailed instructions on filtering the line listing.

Data elements reflected in the Line Listings are summarised in the table below:

Line Listing Data Elements	ICH E2B(R3) Element Reference	Description	Example
EU local number	N/A	EudraVigilance local number, which is an identifier assigned to	EU-EC-12345

Line Listing Data Elements	ICH E2B(R3) Element Reference	Description	Example
		the ICSR in EudraVigilance	
EV Gateway Receipt Date	N/A	EudraVigilance Gateway Date, which is the date of receipt of the ICSR in EudraVigilance	01/01/2014
Report type	C.1.3	Type of Report	Spontaneous
Primary source qualification	C.2.r.4	Primary source Qualification: grouped as Healthcare Professional or Non-Healthcare Professional	Healthcare Professional
Primary source country for regulatory purposes	C.2.r.5	Primary Source for Regulatory Purposes, displayed as EEA/non EEA.	EEA
Literature Reference(s)	C.4.r.1	The literature reference(s) for suspected adverse reactions described in the literature and the corresponding ICSRs in EudraVigilance	Tolerable pain reduces gastric fundal accommodation and gastric motility in healthy subjects: a crossover ultrasonographic study. Hasuo H1, Kusunoki H2, Kanbara K1, Abe T1, Yunoki N3, Haruma K2, Fukunaga M1. Biopsychosoc Med. 2015 Feb
Patient age group	D.2.2a	Mapped against the 'Age at Time of Onset of Reaction / Event', based on the reported patient age or calculated based on difference between 'Date of Birth' and 'First Reaction Start Date' (if available in a valid date format dd/mm/yyyy)	18-64 Years
	D.2.2b	'Age at Time of Onset of Reaction / Event (unit)'	
Patient Age Group (as per reporter)	D.2.3	'Patient Age Group' (as per reporter)	Adult
Patient sex	D.5	'Sex' (gender of the patient)	Female
Parent/Child	N/A	To indicated if this is a report that relates to a parent and a child	Yes
Reaction List PT (Duration – Outcome - seriousness criteria)	E.i.2.1b	'Reaction / Event MedDRA Preferred term' description	Rash (3d – Resolved - Life Threatening, Caused / Prolonged Hospitalisation) Nausea (1d - Resolved) Headache (3d – Not resolved)
	E.i.6a/b	'Duration of Reaction / Event'	
	E.i.7	'Outcome of Reaction / Event at the Time of Last Observation'	
	E.i.3.2a, E.i.3.2b, E.i.3.2c, E.i.3.2d, E.i.3.2e, E.i.3.2f	The seriousness criteria of the reported reaction, e.g. Results in Death, Life Threatening, Caused / Prolonged Hospitalisation, Disabling / Incapacitating, Congenital Anomaly / Birth Defect, Other Medically Important Condition	
Drug List (Drug Char - Indication PT – Action taken – [Duration - Dose - Route])	G.k.1	Characterisation of 'Drug Role', defined as suspect, interacting, concomitant or drug not administered.	PRODUCT [Substance] (S -Dental pain, Headache – Drug withdrawn – [1d –

Line Listing Data Elements	ICH E2B(R3) Element Reference	Description	Example
Or Drug List (Drug Char - Indication PT – Action taken – [Duration - Dose - Route– More in ICSR])		Based on this data element, 2 different 'Drug' (medicines) lists will be created: - for suspect and interacting drugs - for concomitant or drug not administered	0.5mg – oral]) Or PRODUCT [Substance] (S - Dental pain, Headache – Drug withdrawn – [1d – 0.5mg – oral – More in ICSR])
	G.k.2.2	Reported medicinal product, displayed as recoded against the Extended EudraVigilance Medicinal Product Dictionary for centrally authorised products (for non-centrally authorised products, only the recoded substance will be displayed where reported)	
	G.k.2.3.r.1	Substance / Specified Substance Name, displayed as recoded against the Extended EudraVigilance Medicinal Product Dictionary (if not, it will be displayed as reported)	
	G.k.7.r.2b	Indication of the medicinal product described as MedDRA Preferred Term	
	G.k.4.r.6a	'Duration of Drug Administration', as reported or based on 'Drug Administration Start Date' and 'End Date'	
	G.k.4.r.1a/b	Dose of the medicine	
	G.k.4.r.10.2	Route of administration of the medicine	

Missing data will be displayed 'blank' or 'not available'.

By default the individual cases are sorted in descending order based on the 'EV Gateway Receipt Date' i.e. the most recently received case meeting the filtering conditions is the first one returned in the line listing. Users wishing to sort the line listing differently should do so by exporting the data into an appropriate application (See **section 7.6.** instructions on exporting the line listing).

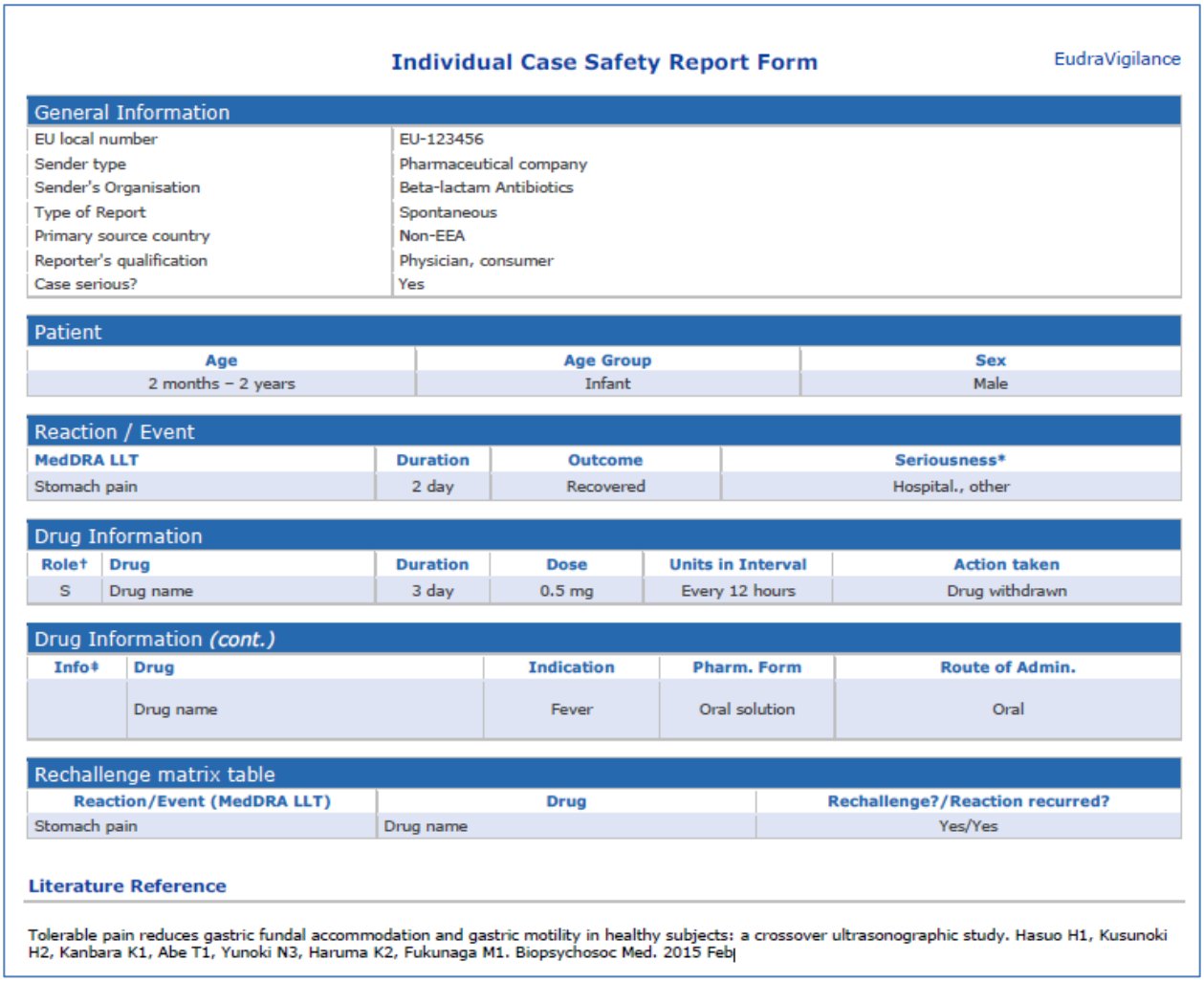
Line Listing Report
Time run: 05/07/2016 14:57:02

EU Local Number	Worldwide Unique Case Identification	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Parent Child Report	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form
EU-EC-7459603	Non EEA-Bristol-Myers Squibb Company-19847243	27/12/2013	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Child	Female	No	Pancreatitis (n/a - Unknown - Caused/Prolonged Hospitalisation)		Not reported	ICSR
EU-EC-7432579	Non EEA-Bristol-Myers Squibb Company-19502665	19/12/2013	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	No	Insomnia (n/a - Unknown - Other Medically Important Condition), Psychomotor hyperactivity (n/a - Unknown - Other Medically Important Condition), Seizure (n/a - Unknown - Other Medically Important Condition)		TRAZODONE HCL [TRAZODONE HCL] (C - n/a - Not Available - [n/a - 50mg - Not available])	ICSR
EU-EC-7427794	EEA-Bristol-Myers Squibb Company-19897735	18/12/2013	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Delirium (n/a - Recovered/Resolved - Other Medically Important Condition), Restlessness (n/a - Recovered/Resolved - Other Medically Important Condition)		Not reported	ICSR
EU-EC-7430882	Non EEA-JNJFOC-20131207478	18/12/2013	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amnesia (31d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Tremor (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation)		SYNTHROID [LEVOTHYROXINE SODIUM] (C - Hypothyroidism - Not applicable - [n/a - 50ug - UNKNOWN])	ICSR
EU-EC-7415220	EEA-LRB-164655	13/12/2013	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	Yes	Paraesthesia (n/a - Not Recovered/Not Resolved -)		OLANZAPINE TABLET 5MG [OLANZAPINE] (C - n/a - Not Available - [n/a - 5mg - ORAL])	ICSR
EU-EC-7389950	Non EEA-Bristol-Myers Squibb Company-19857457	06/12/2013	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	No	Atrial fibrillation (n/a - Unknown - Other Medically Important Condition), Muscle twitching (n/a - Unknown - Other Medically Important Condition), Wrong technique in product usage process (n/a - Unknown - Other Medically Important Condition)		Not reported	ICSR

As it is not possible to include all data elements for an ICSR in the line listing, an ICSR form is also available for further review.

The ICSR form presents the data elements for an individual case as per the EudraVigilance Access Policy (public access).

Data elements in the form are grouped into logical sections (e.g. drug, reaction, medical history) so that the user can easily visualise the available information.



Individual Case Safety Report Form EudraVigilance

General Information

EU local number	EU-123456
Sender type	Pharmaceutical company
Sender's Organisation	Beta-lactam Antibiotics
Type of Report	Spontaneous
Primary source country	Non-EEA
Reporter's qualification	Physician, consumer
Case serious?	Yes

Patient

Age	Age Group	Sex
2 months – 2 years	Infant	Male

Reaction / Event

MedDRA LLT	Duration	Outcome	Seriousness*
Stomach pain	2 day	Recovered	Hospital., other

Drug Information

Role†	Drug	Duration	Dose	Units in Interval	Action taken
S	Drug name	3 day	0.5 mg	Every 12 hours	Drug withdrawn

Drug Information *(cont.)*

Info‡	Drug	Indication	Pharm. Form	Route of Admin.
	Drug name	Fever	Oral solution	Oral

Rechallenge matrix table

Reaction/Event (MedDRA LLT)	Drug	Rechallenge?/Reaction recurred?
Stomach pain	Drug name	Yes/Yes

Literature Reference

Tolerable pain reduces gastric fundal accommodation and gastric motility in healthy subjects: a crossover ultrasonographic study. Hasuo H1, Kusunoki H2, Kanbara K1, Abe T1, Yunoki N3, Haruma K2, Fukunaga M1. Biopsychosoc Med. 2015 Feb

6. Interpretation of web reports

The **running total of individual cases** available in **Tab 1- Number of individual cases** and **Tab 2 – Number of individual cases received over time** is the value that should be used to quantify the total number of spontaneous individual cases that have been reported to EudraVigilance for a selected medicine or active substance.

The information available in **Tab 3, Tab 4, Tab 5 and Tab 6** takes into account the suspected undesirable effect(s) (adverse reactions) reported in an individual case; as an individual case may refer to more than one suspected undesirable effect, the information shown in Tab 3, 4, 5 and 6 does NOT represent the total number of individual cases that have been reported to EudraVigilance, but the number of related undesirable effects.

The table provides an example of the number of running total of individual cases (Tab 1) and how this information appears in Tab 3, 4, 5 and 6

Number of individual cases (Tab 1)	Reported Suspected Adverse Reaction and corresponding Reaction Group(s)	Number of individual cases shown by Reaction Groups (Tab 4 and Tab 5)	Number of individual cases shown by Reported Suspected Adverse Reaction (Tab 6)
1 individual case	Reaction **A** -> Reaction Group **X** Reaction **B** -> Reaction Group **X**	**1** case for Reaction Group **X**	**1** case for Reaction **A** **1** case for Reaction **B**
1 individual case	Reaction **A** -> Reaction Group **X** Reaction **C** -> Reaction Group **Y**	**1** case for Reaction Group **X** **1** case for Reaction Group **Y**	**1** case for Reaction **A** **1** case for Reaction **C**

In this example, the web report shows two individual cases for the medicine or active substance selected in Tab 1; using the classification of the MedDRA dictionary, the suspected adverse reactions are associated to the corresponding Reaction Groups.

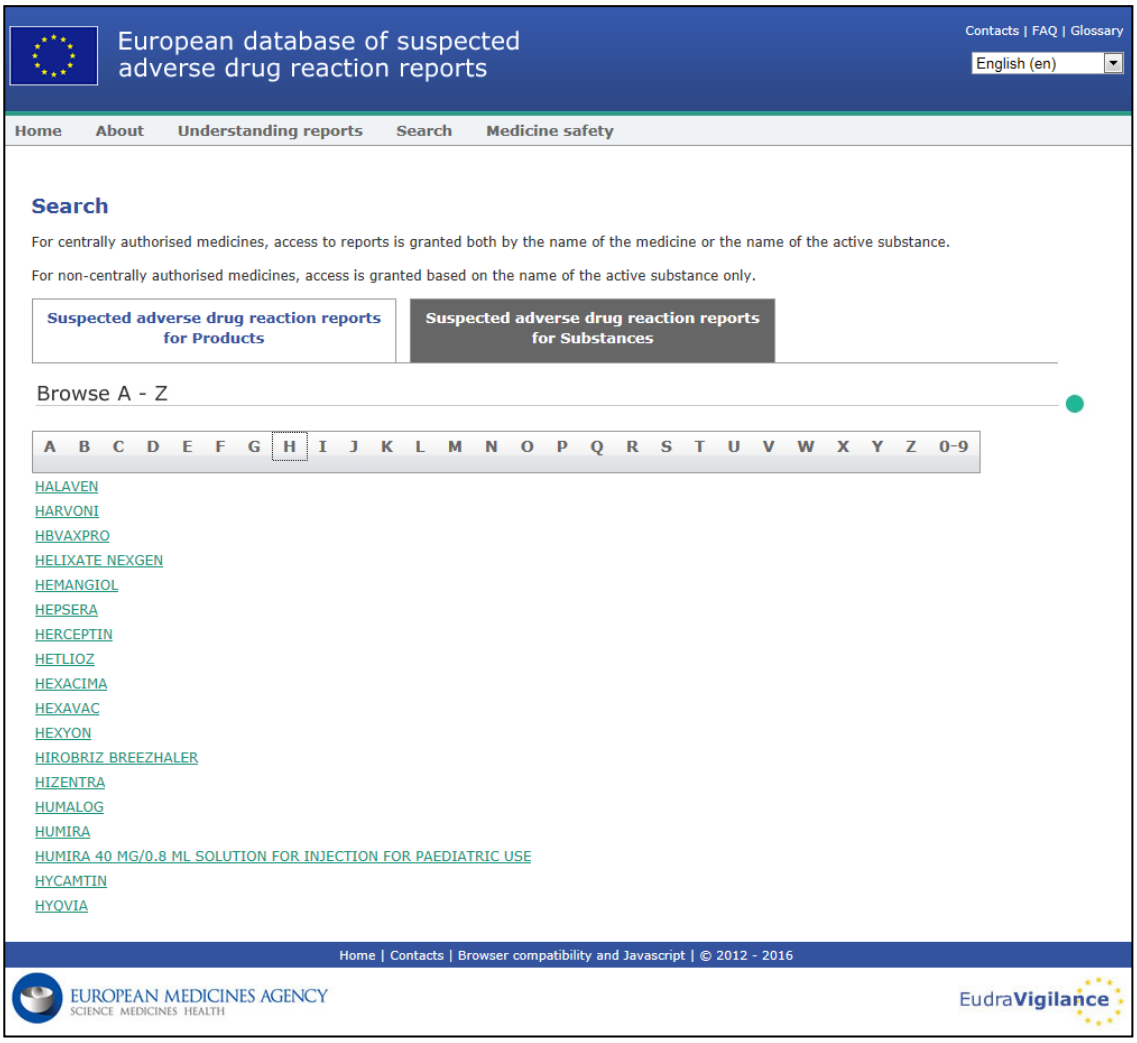
In Tabs 3 and 4, the number of individual cases shown depends on the number of Reaction Groups in each individual case; the same individual case appears as many times as there are distinct Reaction Groups.

In Tab 6, the number of individual cases shown depends on the number of suspected adverse reactions in each individual case; the same case appears as many times as there are distinct suspected adverse reactions.

7. Web report functionalities

7.1. General Navigation

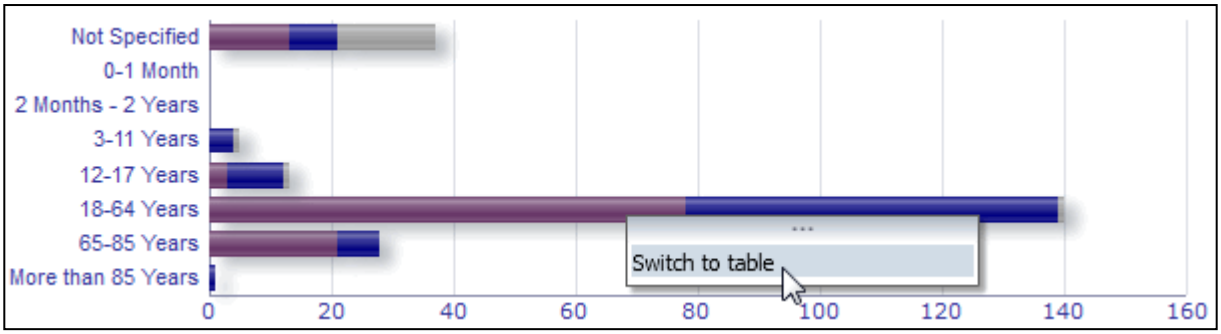
Users of the adrreports.eu portal can access details of the ICSRs submitted to EudraVigilance by name of the medicine (for centrally authorised products), or by name of the active substance of a medicine for non-centrally authorised products). Users can access reports via the Search page of the adrreports.eu portal by selecting a product or active substance from the alphabetical overview menu.



Once a product / active substance is selected, a corresponding web report is launched in the browser. To navigate between tabs, click on the tab of interest at the top of the window.

7.1.1. Graph/Grid view

The web report allows to quickly change from a Graph view to a Grid view (and back) by clicking on the icon.

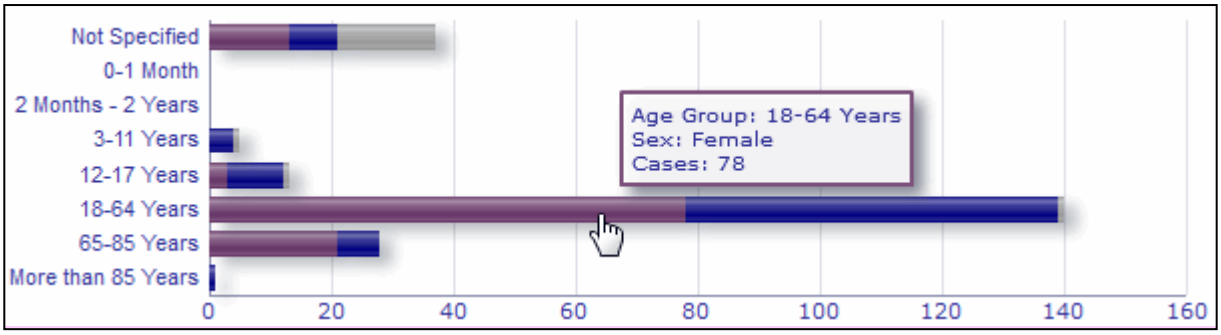


Age Group\Sex	Number of individual cases			Total
	Female	Male	Not Specified	
Not Specified	13	8	16	**37**
0-1 Month	0	0	0	**0**
2 Months - 2 Years	0	0	0	**0**
3-11 Years	0	4	1	**5**
12-17 Years	3	9	1	**13**
18-64 Years	78	61	1	**140**
65-85 Years	21	7	0	**28**
More than 85 Years	0	1	0	**1**
Total	**115**	**90**	**19**	**224**

Return - Create Bookmark Link

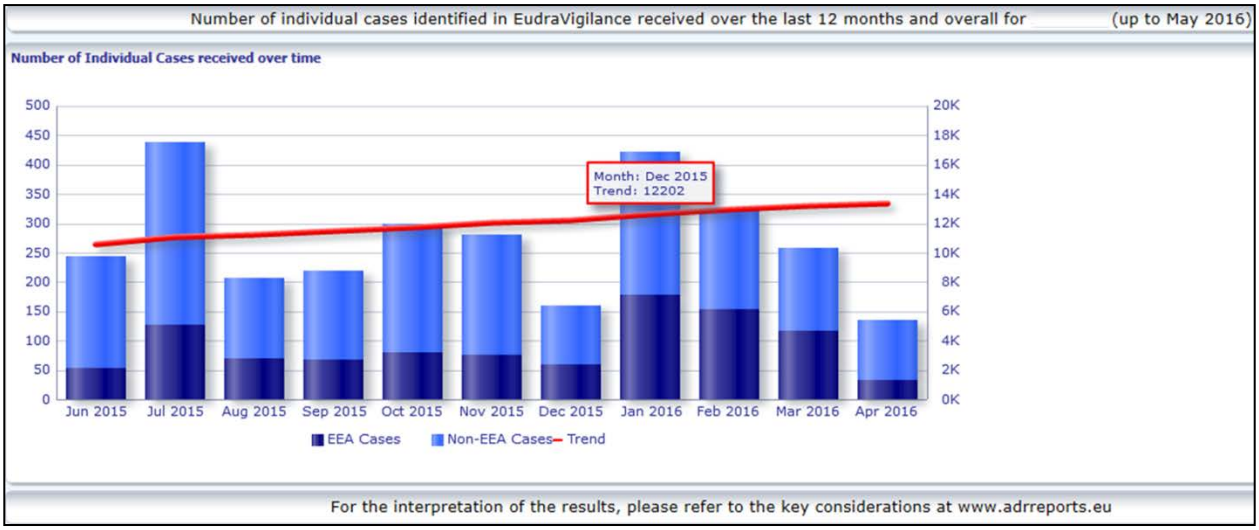
7.1.2. Legend

The Graph view allows visualising relevant information by hovering the mouse over the graph.



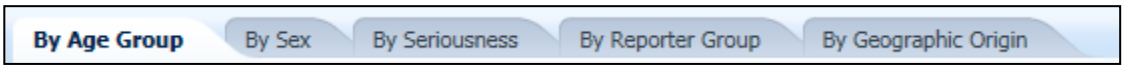
7.2. Navigation in Tab 2 – Number of individual cases received over time

Individual data points on the trend line available in Tab 2 can be viewed by hovering the mouse over the trend line at a position corresponding to the desired month.



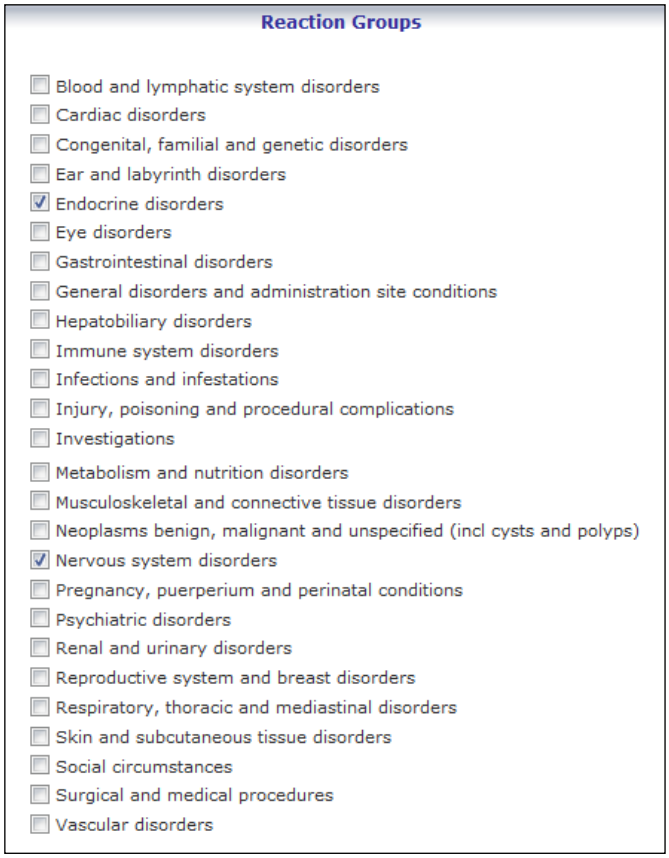
7.3. Navigation in Tab 4 – Number of individual cases by reaction groups

This allows selecting the variable for the reaction group data by using the relevant tab.



7.4. Navigation in Tab 5 – Number of individual cases for a selected reaction group

This allows choosing and clicking on a Reaction Group to view the corresponding information.

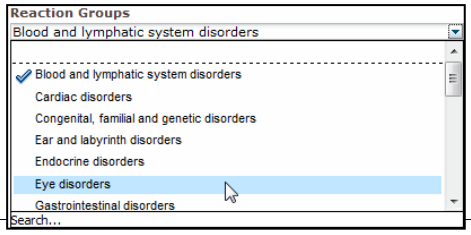


7.5. Navigation in Tab 6 – Number of individual cases for a selected adverse reaction

An interactive selector allows choosing a reaction group and a reported suspected adverse reaction.

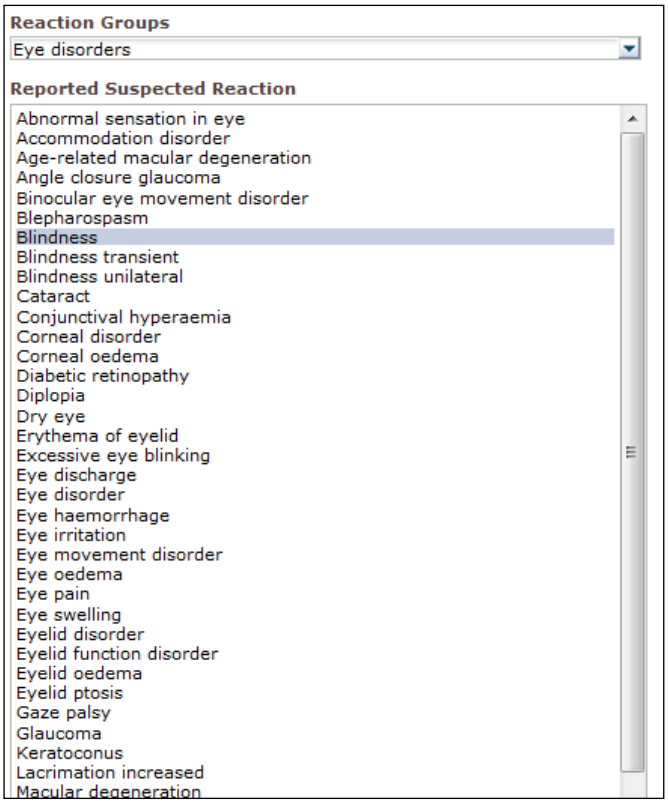
The reaction group and the reported suspected adverse reaction can be selected from the MedDRA dictionary and are part of the same classification:

1. This allows choosing and clicking on a **Reaction Group**:



2. The list of **reported suspected adverse reactions** belonging to that group is updated accordingly;

3. This allows choosing and clicking on a Reported Suspected Reaction to see the corresponding information:

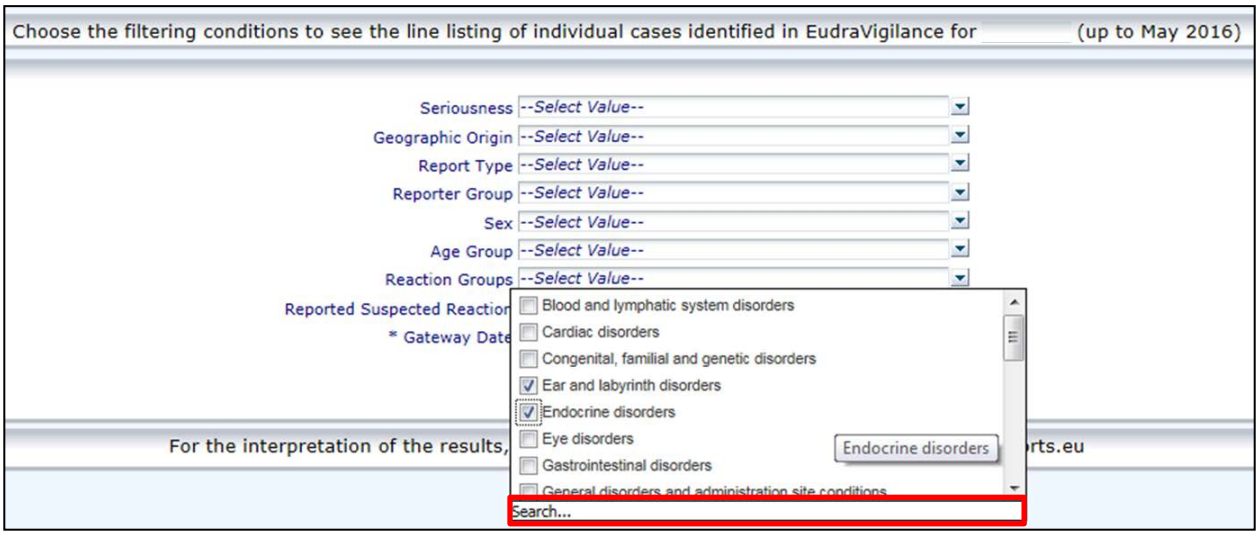


If a reaction group or a reported suspected reaction cannot be found, this means that no spontaneous reports with the undesirable effect (adverse reaction) for this medicine or active substance have been submitted so far to EudraVigilance, i.e. there are no individual cases available.

7.6. Navigation in Tab 7 – Line Listing

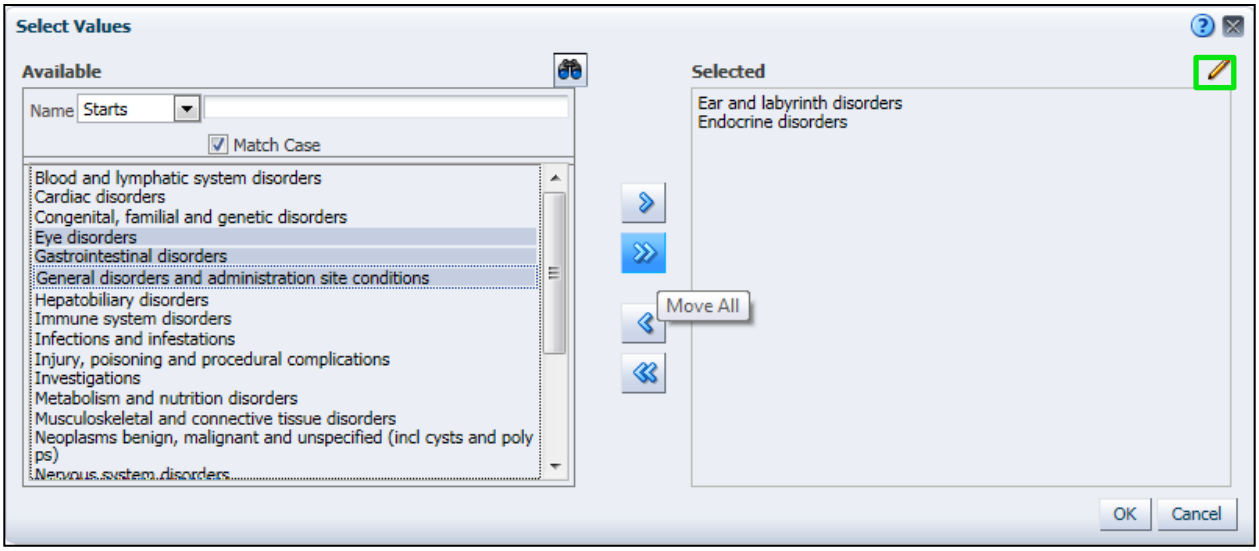
7.6.1. Filtering the Line Listing

A list of nine filtering conditions is available to create a customised line listing of individual cases relating to the selected medicinal product or active substance. If more than one filtering condition is selected, the logical condition will be an 'AND' condition. Clicking on a filtering condition will open a list of all possible filtering options, which can be selected via the appropriate tick-box.

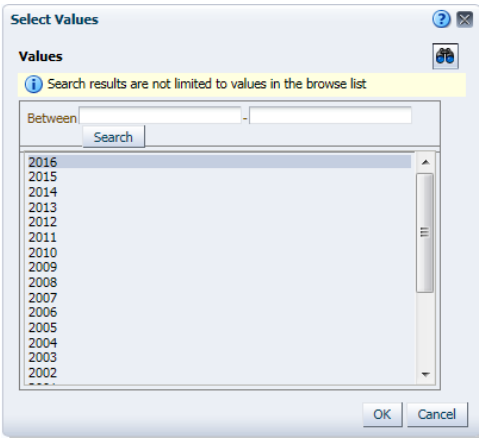


Multiple filtering conditions can be specified using this view or alternatively through the advanced value selection menu. This can be accessed by clicking the “Search…” field at the bottom of any filtering option list (see the section in the red box in the figure above). If the option ‘Match Case’ is selected, the search will be performed for the specific text string in the ‘Search’ box.

This view provides enhanced filtering criteria search functionality, including the ability to search for values starting with, ending with, or containing stated characters, and the ability to select / deselect multiple options. Users can also manually enter a filtering condition using this view by clicking on the pencil icon (see the section in the green box in the figure below) and by typing the condition into the text box.



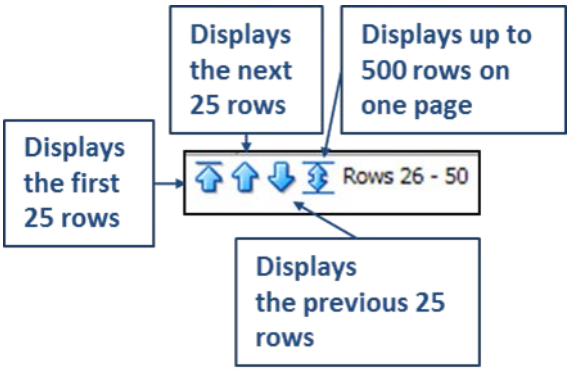
For numerical filtering conditions such as the EudraVigilance Gateway Date, the advanced value selection menu enables users to search for all possible values within the stated parameters (see figure below).



Once all desired filters are selected, users can access the line listing of all pertinent cases by clicking "Run Line Listing Report".

7.6.2. Line Listing and ICSR Form functionality

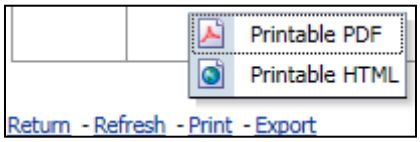
Once a user has submitted their filtering criteria, a corresponding line listing of cases submitted to EudraVigilance will be returned. Details of the data provided in this line listing are explored in **section 5.7.** The returned line listing displays up to 25 reports matching the filtering criteria stipulated by the user. If there are more than 25 cases, users can navigate through the dataset using the buttons at the bottom of each page:



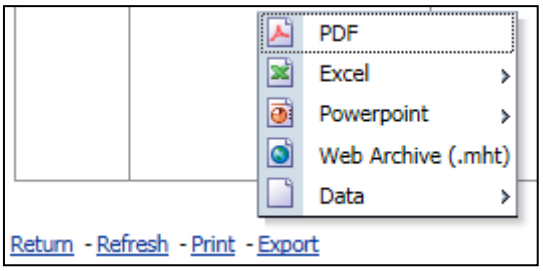
Users can also select other functions using the buttons situated at the bottom left of each page:

Return navigates the user back to the line listing filtering menu detailed in **section 7.6.1.**

Refresh prompts the system to re-apply the previously defined filtering conditions to the live EudraVigilance data set.



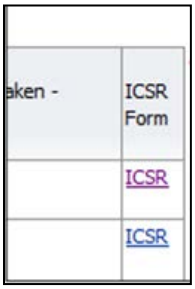
Print presents the line listing in a printable format as either a PDF or html page, based on the user's preference.



Export enables users to download the line listing data into one of file formats listed in the table below:

Export category	Export option	File type
PDF	Adobe Portable Document Format	.pdf
Excel	Excel 2003 compatible workbook	.xls
	Excel 2007+ compatible workbook	.xlsx
Powerpoint	PowerPoint 2003 compatible presentation	.ppt
	PowerPoint 2007+ compatible presentation	.pptx
Web Archive	MIME HTML web archive file	.mht
Data	Comma-separated value file	.csv
	Tab delimited comma-separated value file	.csv
	XML Format	.xml

Downloads are limited to 13,000 rows for Excel 2003/2007 and PDF/PowerPoint; and 100,000 rows for CSV, Tab delimited and XML. An ICSR form is also available for each report included within the queried line listing, when clicking ICSR form in the last column of the line listing.



These can be downloaded as a .pdf file and contain data elements from the ICSR according to the EudraVigilance Access Policy (public access). For further information regarding the data elements included in the ICSR form, refer to **section 5.7.**

8. List of acronyms used in the document

Acronym	Meaning
CSV	Comma-separated value file
EEA	European Economic Area
EMA	European Medicines Agency
EU	European Union
EV	EudraVigilance
ICSR	Individual case Safety Report
NCA	National Competent Authority of an EEA Member State
PT	Preferred Term
SOC	System Organ Class
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
PDF	Portable Document Format
XML	Extensible Markup Language
MedDRA	Medical Dictionary for Regulatory Activities
MIME	Multipurpose Internet Mail Extensions
HTML	HyperText Markup Language

9. Supporting documents

Guidance on the interpretation of spontaneous case reports of suspected adverse reactions to medicines
http://www.ema.europa.eu/docs/en_GB/document_library/Report/2011/07/WC500109582.pdf

EudraVigilance Access Policy -
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2016/12/WC500218300.pdf

EU ICSR Implementation Guide -
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2014/04/WC500165979.pdf