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Veterinary Pharmacovigilance EVVET - Data Warehouse user manual

Version 3.0

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1. Introduction

1.1. About this User Manual

This user manual is prepared to support the use of the business intelligence tool EVVET Data Warehouse (DWH). The document is composed of the following chapters:

- **Chapter 2**: presents a login overview of DWH application and how to access the catalog.
- **Chapter 3:** presents the AER received over a period of time and Organisation dashboard.
- **Chapter 4:** presents the adverse event overview dashboard.
- **Chapter 5:** presents the signal detection dashboard.
- **Chapter 6:** presents the signal evaluation dashboard.
- **Chapter 7:** presents the adverse event comparison between 2 periods dashboard.
- Chapter 8: presents the data stratification dashboard.
- **Chapter 9:** presents the signalling for reactions linked to a product or ingredient dashboard.
- **Chapter 10:** presents the line listing dashboard.
- **Chapter 11:** presents the list of products dashboard.
- **Chapter 12:** presents the Pharmacovigilance inspections dashboard.
- **Chapter 13:** presents the Sales dashboard.
- **Chapter 14:** presents how to group data for different products.
- Chapter 15: provides an oversight of the different dashboards implemented
- Chapter 16: elaborates on KPI's and ROR calculation.

Therefore, the scope of this user manual is to provide detailed explanation on each of the reports that has been implemented and its behaviour.

2. EVVET Data Warehouse (DWH)

2.1. DWH Login

EVVET3 DWH is accessible by clicking on https://bi.ema.europa.eu and using any modern browser.

Users are required to log in using their email address (which can differ for each organisation) instead of an EMA username and password. It is important to note not to use userId with suffix "@id.ema.europa.eu" as EMA has deprecated access like this.



Image 1: Login to DWH application

When signing in it might take the user to another page related to the user's organisation where the user can enter their password, and if there is a single sign in authentication method configured it will result in a successful sign in. However, in some cases it may ask for a code depending on the authentication process in place. Again, this might differ for each organisation.

For more information regarding the authentication methods used please follow the link: <u>Sign In \cdot EMA</u> <u>Account Management</u> where we can find detailed instructions.

	rg	5	Your email address and password
Sign in with your org	anizational account	\square	
name.surname@me	dicinesorg.com 🦯		
Password			

Image 2: Authentication window associated with organisation domain

When a user logs in, the user is prompted to the Home page from EMA Business Intelligence tool, where Oracle BI standard features are displayed (i.e.: user's recent dashboards or analysis among other options):

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Published Reporting Point 36 W Artist	NOCOTI Brokhanski Ugraf islanko-dahimati- 1. Ugraf islanko-dahimati- 1. Straf forstor dahimati- 1. Papis 1 (Korw	Digital datas has dashinad - 5. Caref Mariya Richard and a sensari data Caref Mariya	Figned Andrections Guidinand - Pr. Guine (Native Guine (Native Guine (Native Guine (Native
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Image 3: BI Home page

2.2. Catalogue access

Over the main menu located on the top of the screen, the user can access the datawarehouse catalogue of reports:

Creates	Recent		
	Signal Advection dembloant - 5	Signal Adection Ashboard - 5 Open1 Manee	Sami Adraction, Sachtoard - D.,
	Sparal Actuation Mathematic S., Come (Print)- House Combinateds -	Advent over American Adve. Open Non-	Allong over answer Pilon Goort Nex-
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	Nost Popular		
	() By recommendation are synerity praticity. Post Py Developed R: Coshing Train-	naise terms will be simply, ed here where results because products.	

Image 4: Access catalogue

Depending on whether the user is a national competent authority (NCA) or marketing authorisation holder (MAH) they will see different folders in the catalogue section.

If the user is an **NCA** they should see on the left side of the screen and have access to the following folders:

- 'EVVET3 DWH'
- `EVVET3 DWH NCA'
- `EVVET3 DWH Answers Community'

atalog	
약 🗸 🔞 🕞 🍘 📖 🗸 🚕 🦯 📇 🗸 🏦 🗸 🔀 🎁 📋 Location /Shared Folders	
Folders	Pe C
Shared Folders Answers Community	
EVVET3 DWH EVVET3 DWH Answers Community EVVET3 DWH NCA	

NCA users catalogue access

Image 5:

If the user is an **MAH**, they should see on the left side of the screen and have access to the following folder:

'EVVET3 DWH'



Image 6: MAH users catalogue access

In each of these folders it will contain a subfolder called 'Dashboards' followed by each of the reports pertaining to that folder.

The folder 'EVVET3 DWH' contains the following dashboards (NCAs, MAH, EMA Staff):

- Administrative reports
- Adverse event overview
- Adverse events comparison between 2 periods
- Basic queries- AER & product data overview
- Data stratification
- EMA internal reports
- Line listing

- List of products
- Signal detection
- Signal evaluation
- Signalling for reactions linked to a product or ingredient
- Trends analysis

The folder 'EVVET3 DWH NCA' contains the following dashboards (only for NCAs and EMA staff):

- Pharmacovigilance inspections
- Sales data



Image 7: Dashboard of reports

The next chapters of this user manual will guide the user through each of the above dashboards.

Note: each dashboard can be accessed in different ways, in addition to the abovementioned, such as: searching on the top menu by the name of the dashboard or adding it to your favourites and consult the tab 'Favourites'.

3. ER received over a period of time and Organisation compliance

This dashboard displays several AERs metrics, so the user can get an overview of the data based on correctness, classification or message received date, as well as get the organisation compliance report related to the information set in the filters page.

The dashboard is divided into two tabs: the 'AER received over a period of time' and the 'Organisation compliance report'.



Image 9: AER Received reports

3.1. Filters

Filters for this dashboard are distributed in the following sections:

1. Timing Filters

In this prompt, the user should select the received date range to apply to the dashboards.

2. Geographic Filters

In this prompt, the user can select:

- Region: EEA or non-EEA countries
- Occurrence country

3. Organisation filters

Non-mandatory prompts for selecting the organisation type (MAH or NCA) or a specific organisation.

4. AER filters

Non-mandatory prompt for selecting the submission type.

5. Historical data

No answer is required for this prompt. By default, a snapshot of the day will be set. In case the user needs to have the information as it was in a past date, then it's needed to inform this date in this prompt.

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(Benday)				
		MA ADVAT		

Image 9: Filter options

3.2. AER received over a period of time

In the first tab the user will navigate to the AER received over a period of time, with the following structure:

At the top of the dashboard, there are two drop-down menus for the user to select Correctness and Classification.

ALR received reports		tione Citalog	Central +	Dadhoards + 🎽 New +	🚨 Open 🔹	Speak is /a risesson make mean in
ACR received over a period of time	Organization compliance report					5
	ConstruesSelect Vitur- 💌			Development Selec	e Value (e	ર

Image 10: Correctness and Classification drop-down menus

Below, two pie charts will be displayed:

- **Number of AERs by correctness:** displaying correct reports in green, report with errors in red and report with warning in yellow.
- **Number of AERs by classification:** displaying case report in green, error report in red, nullified report in white and replaced report in yellow.





Below, two more charts will be displayed with the following information:

- Number of AERs by message received date: Showing the number of AERs per message received date on a monthly basis.
- Number of AERs by message received year (last 5 years): Showing number of AERs per message received date on a year basis, always for the last 5-year span.

Right below, two links: Switch to table, for the user to visualise the information in table format and return to filters to go back to the filters page and edit the query or start over. In addition, the user will see the filters applied to the charts by looking at the bottom, as follows:



Image 12: Filters set

3.3. Organisation compliance report

In the second tab the user will navigate to the Organisation compliance report, with the following structure:

At the top of the dashboard, there is a series of checkboxes for the user to select: Animal/Human, Seriousness and Information Type.

- Right below, two pie charts are being displayed:
- Message received date is set to the original received date.
- Message received date to the most recent information date.
- Both represent compliant in green, and non-compliant in red.



Image 13: Received date to original and most recent charts

Above the charts, the user will find a drop-down menu to jump between organisations. Right below, two links: 'Switch to table', for the user to visualise the information in table format, and 'Return to filters' to go back to filters page and edit the query or start over.

Additionally, the user will see the filters applying to the charts by looking at the bottom, as follows:



Image 14: Filters set

Lastly, by clicking on the sections of both pie charts the user will get the chance to navigate to the line listing reports:



Image 15: Line listing view

And the Reports and duplicates:

Si Gi Magher	ned Duplicate report lat	
5249 84	1249	
5511 Au	5503	
5547 No	5482, 5547	
8052 No	6053	
8296 Tes	3546, 8296	
7603 No	7603, 9857	
19091 No	28091, 3279	
19623 50	29623, 22138, 4674	
19625 50	29625, 22140	- 10
20305 No	20305, 2358	
20469 No	20469	
20471 No	20471	
20475 No	20475	
20476 Yes	20476, 20478, 2508	
20478 No	20474, 20478, 3508	
21837 No	21837, +403	
21949 50	21949	
21953 No	21953, 4089	
21995 No	21955	
22124 80	22124, 5134	
221330 No	22530, 5448	
22138 No	22130	
221239 Tes	19623.22138.4676	

Image 16: Detailed view

4. Adverse event overview

This dashboard displays several quantitative metrics, so the user can get an overview of the data for a product, substance or group of products in terms of number of cases, animals affected, animals died or fatal cases for the selected period.

The dashboard also contains links that allow the user to navigate to the signal detection dashboard, Current Product and Associated Products detail tables, as well as get ROR-based calculations related to the parameters previously set in the filters page.

The dashboard is divided into two tabs, the 'Filters' tab and the 'Adverse Event Overview' tab, in which the user gets to see the result of the query.



Image 17: Adverse event overview menus

4.1. Filters

1. Choose from all attributes in the product information (required)

In this prompt, the user can select at what level of the product hierarchy you want to run your query. These levels are:

- Active substance level: results will be related to AERs for products that contain the selected active substance(s).
- **Product Short name:** results will be related to AERs for selected product(s) grouped by the product short name.
- **ATCVet code level:** results will be related to AERs for products belonging to the selected ATCVet Code.
- **Reported Brand Name:** results will be related to AERs for a selected Product Brand Name as reported in the AER verbatim, prior to standardisation.
- **Product Authorisation Number:** results will be related to AERs for selected product(s) grouped by the product authorisation number stated in the product dictionary.
- **Reported Authorisation Number:** results will be related to AERs for selected product(s) grouped by the product authorisation number as reported in the AER.
- Product composition level (Composition, Strength, Formulation, Pharma Product): results will be related to AERs for products that are composed solely of the selected active substance(s), active substance(s) + strength(s), Active substance(s) + Pharmaceutical form(s), Active substance(s) Strength + Pharmaceutical form. This enables users to group products based on their composition, regardless of the trade names of the products.

Active substance	Select Value	~
Product short name	Select Value	~
ATC vet code	Select Value	~
Reported brand name	Select Value	~
Product authorisation number	Select Value	~
Reported authorisation number	Select Value	~
Product composition (Type = Composition)	Select Value	~
Product composition (Type = Strength)	Select Value	~
Product composition (Type = Formulation)	Select Value	~
Product composition (Type = Pharma Product)	Select Value	~

Image 18: Filter criteria

2. Message received date range (required)

In this prompt you select a range of dates.

2. Message re	eceived date range (Requ	iired)		
Mess	age received date Between	03/08/2021	103/09/2021	20

Image 19: Message received date filter

3. VedDRA hierarchy

In this prompt you select one or multiple VedDRA terms at different levels.

Voi01A Tore 500 -Selad Value-		VotOnA Torm 500 -Selast Value-
VoidONA Torre HUT -Selad Value-		VolDNA Torn HD* -Selad Value-
Vector Term FT -Selad Value-	cit.	VecDRA Term FT -Selad Value-
Weddink Terry LDT - Skilled Value-		Weddek Town LDT -Selast Value-
Use the shap stores on the left acts to faller to some or matche (m2D00) terms. When we had 4400 many the days shows an it will be all resum all many shows at hear own of the source left 10 adds at left, all some than one terms is invalided in the many level. In the out of the source of the source 10 adds at left.	ing only one bette in each level, the query of neuro-scienced loss been reported (1981), areas where at hear one of the UNDON's be	til nånn af osse obere for (n2004) flerar seksted bere beer op sted straffsreve en sekster het beer recordet (021)

Image 20: VedDRA hierarchy filter

4. Report filter (required)

Select whether your result should contain only **animal** or **human** AERs by ticking the relevant option, or both, by selecting both Animal and Human.



Image 21: Human or animal filter

5. All cases or new cases (required)

In this prompt, the user will have to select one of the two options ("All Cases" is selected by default). Selecting "New cases" will return data related only to **new reports** received in EVVET during the selected period and will exclude from the data set follow-ups to reports initially received in EVVET prior to the selected period.

cases or new cases (Required)

Image 22: All or new cases filter

6. Choose from the list of optional AER filters

No answer is required for this prompt. By applying any of these filters, the results dataset will be restricted to AERs that meet the selected conditions.

Age (hours) >=Select V	lalue 💌	Gender	Select Value 👻	Original n	eceived date Batwaan	03-	16
<=Select V	alue 💌	Species	Select Value 💌	Start date of re	action/event Between	G3-	B
Age (days) >= ··Select V	alue 💌	Breed	Select Value 💌	Authorisatic	on procedureSelect Value		
<=Select V	alue 💌	Occurrence region	Select Value 🐱	Info	mation typeSelect Value		Y
Age (months) >=Select V	/alue 💌	Occurrence country	Select Value 💽	Primary source ca	stegorisationSelect Value		
<=Select V	alue 🖌	Organisation	Select Value 😿	Is use accor	ding to labelSelect Value		
Age (years) >=Select V	alue 🕑	Report type	Select Value 🐱	Exclude las	ck of efficacy 🗍 Yes		
<=Select V	lalue 💌			Hide known Ve	edDRA terms. 🗆 Yes		
Is off label							
Indication View	Produ	t expired 🗆 Yes 🗌 No	Sto	rage 🗆 Yes No	Treatment View	Other Issue Ves	
Overdosed C Yes	Route	of admin Ves	Species ta	rget 🗆 Yes	Underdosed 🗆 Yes		



- Original Received Date: date that the MAH or NCA first received the message.
- Serious: the system will return only the serious or the non-serious reports.
- **Information type vs Exclude lack of efficacy**: if you want to exclude the lack of efficacy cases and you exclude "Lack of efficacy" within the Information type drop-down menu (by including all other information types), you will get the reports where LOE has been reported together with other issues/information types. However, if you tick the box "Yes" in "Exclude lack of efficacy", the system will exclude those reports where the VedDRA term "Lack of efficacy" has been reported.

7. Threshold ROR (Required)

This prompt is mandatory but filled by default with ROR >= 2, ROR(-) >= 1 and Number of cases >= 3. The user is able to customize these values for the purpose of the analysis.

ROR >= 2	ROR (-) >= 1	Number of cases >= 3



8. Historical data

No answer is required for this prompt. By default, a snapshot of the day will be set. If a different date is selected, the results will reflect the data in EVVET as per the date selected, excluding data received after the selected date.

Snapshot from	03/09/2021	61
		Reset +



4.2. Adverse event overview

The Adverse Event Overview tab shows the result of the query, grouped in a series of charts of different kinds, as well as a header including some key figures, together with a filter for selecting Species. A summary of the filters applied is also available at the very top, so the user is able to have this information in sight while doing the analysis.

Every chart has a title on top describing the content and sometimes a clarification about the information included (between brackets) and a little disclaimer at the bottom in case additional details are required.

Test Aller and water			
	Table of analysis formation (see a 40,0000) and Charana primation (see a 40,0000) and Charana (see a 40,0000) and Charana (see a 40,0000) and Charana (see a 40,0000) and Charana (see a 40,0000) and Age Binon.	a) Den Den Hannen titel (2 fri den den 2003 (4 fri den	
	Arman winter	dia- X	
traction of same 499	Sands Period 56,801	Fold same 442	Romah Gail 32,770

Image 26: Adverse event overview results

The charts displayed in the Adverse Event Overview tab from top to bottom are as follows:

- **Number of cases by region (Specified period):** the pie chart shows the number of cases by EEA and Non-EEA for the period specified on the filters page.
- **Number of cases by region (All cases):** the pie chart shows the number of cases by EEA and Non-EEA, but not limited to the period specified on the filters page.



Image 27: Number of cases (period vs all time) charts

By clicking on any sector of the pie chart, the charts will break down on EEA/Non-EEA countries, with a link enabled to go back to previous state, just as follows:



Image 28: detailed chart view at country level

- Number of cases and fatal cases (LAST 10 YEARS): the bar chart shows the number of cases and fatal cases for the last 10 years, not applying the message received dates included in the filters page.
- Number of fatal cases over average (LAST 10 YEARS): the line chart shows the number of fatal cases over average for the last 10 years, not applying the message received dates included in the filters page.





By clicking on any bar, the chart will give the user access to a see details functionality. A new tab will open up with a detailed table containing several metrics for that specific year and product at VedDRA PT level, just as follows:



Image 30: VedDRA level detailed line listing

At the same time, by clicking in the blue line of the right chart, for a specific year, the user navigates into that year's 12 month-span, just as follows:





- Number of cases by species and VedDRA SOC over product: the heat map shows the cases classified by species and VedDRA SOC for the product selected in the filters page. This table uses a different tone of blue depending on the number of cases. The larger the quantity of cases for that species and reaction, the darker the blue.
- Number of animals affected, and animals died (LAST 10 YEARS): the bar chart shows the number animals affected and died over the last 10 years, not applying the message received dates included in the filters page.

	1	Corte	184	taria.	ALC .	in the second se	7.84
App - policy of a dearfeets		-	£1	1.1			
Referenced descripts	1						1.0
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Equiliplies Annulari	4	1	17			10.00	12,881
Eye desiden			4	1		and the second s	
Netwo-offen; depotes			3				
Service substrationales		2	28				1. W
Trailprice		1 21	11				
Navalacian and rustifies also also			X				((a))
Real Markets at and re-			2	10.0			
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Real and union Standers Reproduction Standard			-				Parameter segments
Resident Sol-clear Act			4	12		1.1	Revise 2 could a part Revise a start of
pice and appendages deprotent			3				
Ryseric diseases	1		24	3	4	3	"Neutral and the first sector of the first sector of
lanuar lade area			2				



Both charts have second level reports: in regards of the heatmap, the user will get access to the See Details table with detailed information, to the Signal Detection dashboard through the Animal/Human adverse events overview as well as to the Associated medicinal products & VedDRAs in the last of the options displayed in the drop-down menu.



All three second level reports will show the information in regards of that set of specific cases.

Image 33: Number of cases by species and VedDRA SOC over product

By clicking on any of the bars of the bar chart, the user gets to navigate to the ROR calculation using animals affected for the year selected:



Image 34: Animal affected over died chart





At the bottom of this tab, we find a series of links with different functionalities:

4.2.1. See details

By clicking on see details the user navigates to a new window with the detailed information for the filters included in the query. At the top, the user will also find both Product Hierarchy and VedDRA hierarchy level drop-down menu as well as a Species filter to switch between potential species related to the product or products involved in the analysis.

Species Ost	~										
Medicinal product, shortname	VedDRA SOC name	VedDRA PT name	ROR	RDR (+)	ROR (-)	Number of animals affected	Number of cases (period specified)		Number of NON EEA cases (period specified)	Number of EEA cases (period specified)	Number of c (Total ALL)
DRAXOEN	Behavioural disordem	Anviety	N/A	N/A	N'A	1		1	0	1	
	Behavioural disorders	Vocalisation	N/A	N/A	N/A	1		1	0		
	Digestive tract disorders	Emess	N'A	N/A	N/A	1		1	1)
	Eye deorders	Abnormal vision	N/A	N/A	N'A	1		1	0	1	
	Investigations	Aniemia NOS	N/A	N/A	N/A	1		1	1	(2
	Investigations	Elevated parcreatic anzymes	N/A	N/A	N/A	1		1	1)
	Investigations	Elevated total bilirubin	N/A	N/A	N'A	1		1	1	(C) (C)	1
	Investigations	Leucopenia	N'A	N/A	N/A	1		1	1		1
	Investigations	Other abnormal tast	N/A	N/A	N/A	1		1	1		1

Image 36: Detailed view

The see details table include the following columns: *Medicinal product shortname, VedDRA SOC, VedDRA PT, ROR, ROR(+), ROR(-), Number of animals affected, Number of cases (period specified), Number of non-EEA cases (period specified), Number of EEA cases (period specified), Number of cases (Total ALL), Number of NON EEA cases, Number of EEA cases, Number of cases (Total ALL reactions), Number of fatal cases (period specified), Number of fatal cases, Reaction count, Case count by product (filter applied), Case count (filter not applied), Reaction count total, Percentage of reactions and Percentage of cases.*

What's more, the See Details table includes second level reports which is enabled at the Number of cases (period specified) column, just as follows:

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Image 37: Detailed view

By clicking over any number, the user will have access to the following functionalities:

• **Line listing**: A new tab will open with the most detailed table the user has access to, basically with full information about the cases of the line selected.



Image 38: Line listing view

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			C53269 Victorial de la vergeral repetier alle soft- repetier de la vergeral could versit il related Victorial i related Victorial i prisera could versit i prisera		

Image 39: Line listing view

- List of principal and report duplicates: A new tab will open with a detailed table including the duplicate reports, if any.
- Case listing with VedDRA terms aligned: The user can see the list of cases with VedDRA terms aligned and the number of animals affected involved.

Case lis	sting with VedDRA terms al	igned - Overview of AEF	દ
AFR Id	Case number	Number of animals affected	Application site disorders Number of cases
/ LICES			2
388428	USA-PFZRCVMP-2018-US-54479	1	1
504810	ZAF-MERCKMSD-2019-ZA-00608	35	1
<u>Return</u> -	<u>Analyze</u> - <u>Refresh</u> - <u>Print</u> - <u>Export</u>		

Image 40: Case listing with VedDRA terms aligned view

4.2.2. Links to signal detection reports

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Image 41: Links

4.2.2.1. Animal/Human adverse events overview

This link allows the user to navigate to the Signal Detection and visualise this dashboard applying the same filters selected for the purpose of the current adverse event analysis.

4.2.2.2. ROR calculations based on number of animals reacted

This link allows the user to navigate to the ROR calculation using animals affected applying the same filters selected for the purpose of the current adverse event analysis. This table shows a group of ROR metrics related to the animals affected for a preset product and dates.

Species Cor									
indicinal product shortharne	VixDRA SOC name	Animals affected RDR -	A Animals affected ROR	8 Animals affected ROR	C Avinals affected ROR	D Animals affected ROF	(-) Animals affected	ROR Animals affected ROR	(+) Message received dat
RADON	Believiceral disorders		1	0	0	15	N/A	NGA .	N/A 12/06/2018
	Digestive stort disorders.		1	0	2	77	N/A	N/A	N/A 22/11/2019
	Eye disorders		1	0	3	55	NOA.	N/A	N/A 17/11/2015
	Investigations		1	0	6	£3	N/A	NA	N/A 22/11/2019
	Neurological disorders		1	0	21	37	N/A	N/A	N/A 07/11/2016
	Neurological disorders		1	0	1	14	N/A	N/A	N/A 12/06/2018
	Respiratory tract disorders		1	0	27	62	NA	16'4	N/A 22/11/2013
	Symmic deciders		1	0	20	5	N/A	NA	N/A 12/06/2015
	a new dand						* ****	auta	anta under famme

Image 42: ROR calculations based on number of animals reacted table

4.2.3. Link to data stratification report

4.2.3.1. Adverse events overview for associated products

This link allows the user to navigate to the data stratification report, displaying 2 different tables: The first one for the product selected in the filters page, detailing number of cases for the product, VedDRA SOC and the species set in the filter. The table also displays ROR(-), ROR(+) and ROR metrics for the product selected.

The second table shows the same information but, in this case, including the associated products (to the one selected in the filters page) and the metrics will be measuring the combination of both products instead of the product selected. The user will also find the reaction count and the number of animals affected columns.

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Image 43: Link to data stratification dashboard

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Image 44: Adverse events overview for associated products view

5. Signal detection dashboard

5.1. Signal detection pre-calculations

Through the pre-calculations functionality in Signal detection dashboard, it will be possible to get the results faster than using the common Signal detection dashboard, as these have been precalculated for the following predefined time frames (using a single product, active substance or product grouping):

- 1 year
- 6 months
- 3 months
- 1 month

5.1.1. Pre-calculations at product short name level in Signal detection dashboard

Signal detection	Nanc, Colaky, Karanka v Grankanski 🖍 Nan v 🎯 ogen v Signal (z. Al 🔤 🖬 🔤 🗮 🔂
	Signal detection dashboard
	Please aelest the type of assish to perform
	Defruit option Send detector - Provisioned 502 Defruit option

Image 45: Product shortname pre-calculations in Signal detection dashboard

'Signal detection Precalculated ROR by product' is the default option pre-selected in signal detection dashboard.

Ngevil distoction - Presidentiated ROR by preduct shortname	hono calag haankar- baabacda v <mark>s</mark> idar- signal bi As Bi G
	Signal detection precalculation dashboard
* Wease fill is at least the product shortness field (horses data are included	e .
1. Product Information (Required)	
Product short some	Precidentations at product shortmerne level work onlytor a single product
6. Threshold ROR (Required for signal detection and static ROR)	
ROR >=[2 ROR () >=[1	Number of cases s= 3

Image 46: Product short name filter in pre-calculations Signal detection

When using the pre-calculations functionality, we should select a single product as the pre-calculations cannot be done for more than one product.

-													
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Image 47: Predefined time frames for pre-calculations

Note: Pre-calculations are done considering the last day of the previous month. Example: If we run the pre-calculations during April, all the time frames pre-calculations will retrieve the data until 31 March.

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docadion	Atelecteda		0	ALC .	N/A	ALCR.	1		10.54	58.4	1614	
	398,000	8	0	1.17	2.35	4,75	8	6	1.17	2.36	4.75	
	Reaches		0	1.05	2.50	4.83	*		124	2.50	4.83	
	South and see as a flammation		0	6.04	N/A	6.(A)	1	3	N(A	164	16.54	
	Cough		0	1.55	2.15	2.86	55	50	2.68	2.18	2.55	
	Dry soos		0	1.52	4.35	15.36	3	3	153	4,00	15.37	
	Oyohosis		0	6.08	14/14	A.C.	1	1	H(S)	MV.	PLAN .	
	Departmen		D	12.6	1.25	1.55	284	2.5	2.4.4	1.25	2.55	
	5.6.60		0	1.52	2.55	4.14	12	32	1.22	2.55	1.21	
	Pears in respiratory tract		0	ALX.	N/A	A.A.	1	3	11.14	10.4	PENA.	
	in draft a na		0	1.22	3.54	5.04	9	5	122	3.01	5.84	
	Hypephetic traches		0	AD:	14/14	N.63.	1	1	H(SA)	567.	PESN	
	Market		0	6.08	14/14	5.(R	1	1	H(la	10.4	re La	
	Centrapor Instation		0	6.08	N/A	6.(A.	2	2	NSA.	10.4	PE-SA	
	Lenegits		0	ALCA.	N/A	ALCR.	2	2	N/A	10.4	751.4	
	Nacel cavity cloorder NOS		0	ACR.	N/A	A.O.	1	1	H(SA)	564	14.55	
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	Accords		0	6.0	84 ¹ 0	5.(R	1	3	R(a)	10.4	reta .	
	Minutes surgedue	,	0	0.37	1.15	3.58	3	3	3.37	1.15	3.55	
	Pulmonary deceder NOS		1	0.47	L.25	3.36	3	3	1.39	0.95	2.55	
	Pulmonary heartorthage	Q2 1 84 M	ra 0	6.67	L.95	4.39	c	¢	2.63	1.90	4.41	
	Pulmonary orderna		Line Dollars	6.44	1.44	1.80	-		2.44	6,94	1.82	
	Kale .		CRC-00-1	1.00	2.35	4.05	18	38	2.55	2.38	125	
	Report along the end of the second of the se		0	1.77	2.55	3.67	50	28	1.77	2.55	3.65	
	Respiratory tract Infection 1805		0	2.12	5.74	15.04	4	5	2.12	5.76	15.65	
	Rivinitie		0	ALC: N	N/A	ALCR.	1	4	10.54	5614	16.54	
	WHERE WE		0	A.C.N.	845	1.58	1	1	H(S)	56%	19.55	
	Second		0	1.61	2.89	4.42	16	38	2.6.5	2.00	1.12	
	Tarborners		0	1.04	1.21	2.13	317	113	3.44	1.25	2 31	

Image 48: Line listing functionality in pre-calculations

When clicking on the 'Number of cases between date 1 and date 2' values, it's possible to get the line listing for the selected value.

5.2. Signal detection dashboard

This dashboard displays several number of cases and animals affected as well as ROR metrics, so the user is able to get an overview of the data for a product, active substance or group of products for a selected period in order to check for potential signals.



Image 49: Signal detection menu

The dashboard is broken down into four tabs: Overview of AERs per product /active substance/ATCVETVET, Signal detection (with 2 RORs, up to Date 2 and up to Date 1) and Static ROR Evaluation as well as the tab for filtering the query (Filters).

1. Filters choose from all attributes in the product information (required)

In this prompt you select at what level of the product hierarchy you want to run your query. The levels are:

- Active substance level: results will be related to AERs for products that contain the selected active substance(s).
- **Product Short name:** results will be related to AERs for selected product(s) grouped by the product short name.
- **ATCVet code level:** results will be related to AERs for products that belong to the selected ATCVet code.
- **Reported Brand Name:** results will be related to AERs for a selected Product Brand Name as reported in the AER verbatim, before standardisation.
- **Product Authorisation Number:** results will be related to AERs for selected product(s) grouped by the product authorisation number stated in the product dictionary.
- **Reported Authorisation Number:** results will be related to AERs for selected product(s) grouped by the product authorisation number as reported in the AER.
- Product composition level (Composition, Strength, Formulation, Pharma Product): results will be related to AERs for products that are composed solely of the selected active substance(s), active substance(s) + strength(s), Active substance(s) + Pharmaceutical form(s), Active substance(s) Strength + Pharmaceutical form. This enables users to group products based on their composition, regardless of the trade names of the products.

Active substance	Select Value	
Product short name	Select Value	
ATC vet code	Select Value	
Reported brand name	Select Value	
Product authorisation number	Select Value	
Reported authorisation number	Select Value	
Product composition (Type = Composition)	Select Value	
Product composition (Type = Strength)	Select Value	
Product composition (Type = Formulation)	Select Value	
Product composition (Type = Pharma Product)	Select Value	

Image 50: Filter options

2. Message received date range (required)

In this prompt you select a range of dates.

Message received date Between 15/08/2021	- 15/09/202	1 0

Image 512: Message received date range filter

3. Report filter (required)

Select whether your result should contain only **animal** or **human** AERs by ticking the relevant option, or both by selecting both Animal and Human.

5. Report filter (Required, only apply for signal detection and static ROR)	
Human or animal 🗆 Animal 🗍 Human	

Image 52: Report filter

4. Optional report filters

No answer is required for this prompt. By applying any of these filters the results dataset will be restricted to AERs that meet the selected conditions.

Age (hours) > = - (mint)	dur-Ini	Gender - Seincr Value 3	f. Original received date	Betweeri .	10-	
en - Seinet V	de la s	species delect value-	5 Start date of reaction/event	Betweer	33-(
Age (days) = - Color V	dan-lai	Breed -Seller Value- Je	 Authorisation procedure. 	-Saled Value		14
en -Seint V	dur-i di Occurrence	report -Select Visite-	 Information type 	-Select slabe-		<u>]</u> .
Age (months) == Scient vi	Fire . Occurrence	puntry delict vision -]	 Inimally source categorisation 	-Solnit Value-		1.
and -Seinet Vi	nive- 16 Organ	satur - Select Hiller-	Is use according to label	-Solect Value		34
Age (years) >=	the let app	rt type - Select Vote- 1	5 Exclude tack of efficacy	Cites		
ex_frint V	ternist .	ferreus : finiter information	5 Hide known VedORA terms	C Yes		
Is off label						
Indication Cities	Product expired	Yes 5	torage Ves The	atment T Yes	Other lance. Ves	
() No		No	_ fee	() No	O No.	
Contraction of Tex	Boote of admin	Yes Seates	target Cives Unde	record Ves		



- Original Received Date: The date that the MAH or NCA first received the message.
- Serious: The system will return only the serious or the non-serious reports.
- Information type vs Exclude lack of efficacy: If you want to exclude the lack of efficacy cases and you exclude "Lack of efficacy" within the Information type drop-down menu (by including all other information types), you will get the reports where LOE has been reported together with other issues/information types. However, if you tick the box "Yes" in "Exclude lack of efficacy", the system will exclude those reports where the VedDRA term "Lack of efficacy" has been reported.

5. Threshold ROR

This prompt is mandatory but filled by default with ROR>=2, ROR(-)>=1 and Number of cases>=3. The user is able to customize these values for the purpose of the analysis.

ROR >= 2	ROR (-) >= 1	Number of cases >= 3



6. Historical data

No answer is required for this prompt. By default, a snapshot of the day will be set. If a different date is selected, the results will reflect the data in EVVET as per selected date, excluding data received after the selected date.

Reset ~



5.2.1. Overview of AERs per product/active substance/ATCVETVET

The number of cases and number of animals affected can be seen in this first tab, distributed geographically in a map, including a drop-down menu on top to jump from one metric to the other. The darker the blue, the more cases associated with a specific country.



Image 56: Overview of AERs per product/active substance/ATC vet

Right below the map, the user will find a much more detailed table with the number of cases and number reacted for the product selected, split by occurrence region and country. In addition, Human or Animal and Seriousness flags will be also displayed, as well as the totals for number of cases and number reacted for each country included in the outcome.

		Human or animal	Animal	Animal	Animal	Animal	Number of cases	Number reacted
		Salaustan	Yes	Yes	No	No		
			Number of cases	Number reacted	Number of cases	Number reacted		
fedicinal product shortname	Octumente region	Octumence country						
BLACTIS	EEA.	Austria	-4			-7		13
		Belgium	7		2	2	,	14
		Casch Kepublic	1		1	2		1.14
		Denmark	41	72		41	8.0	12
		Estonia			2	27	2	2
		France .	- 34	27		5.2	29	3
		Germany	33	29	21	- 32	43	6
		Greece	- 2	1			3	1.00
		37eV	1.7	25		:25	12	
		Luxenbourg		1				21
		Netherlands	19	24	. 16	28	35	5
		Fuland :			1		5	
		Spain	7	1. 2.4		\$7	15	21
		United Kingdons	- 6	4	1)	15	17	2
	Non 884	Braci		4	3	3	7	1
		Hevice			3	7	2	1
		Automiand.					1	

Image 57: Number of cases and number reacted for the product selected detail

By the drop-down menu on top of the table, the user will be able to jump from Medicinal product shortname to Reported brand name, product composition, active substance or ATCvet code visualisation.

		Human or animal	Annal	Animal	Asimal	Asimal	Number of cases	Number reacts
		Bene 1)	Yes	Tes	No	Pro .		
			Number of Gees	Number reacted	Number of cases	Norder readed		
vduct comparition	Octumence region	Documence country						
ABERGOLINE	EEA .	Austria	4			7		1
ABEROOLINE	EEA .	Belgium	7	. 54	- 3	1		
ADEROOLINE	EEA	Coach Rapublic	3	2	1	1	3	
ABEROOLINE	433	Denmark	- 41	. 72	38	61	80	13
ABEROOLINE	804	Estoria			2	- 27	2	
AMERICOLINE	8EA	Piante	24	27			29	3
ARERGOLINE	86A	Gervary	22	29	21	84	43	
ABEROOLINE	46A	G-secs	2	4			2	
ABEROOLINE	EEA.	Tarly	7	13	- 1	25	12	4
ABEROOLINE	EEA	Luterbourg	1	1			1	
ABEROOLINE	#E4	helierlands	19	- 24	34		33	3
ABEROOLINE	EEA .	Polarid					5	
ARERGOLINE	864	Spain	2			- 17	15	3
ABERGOLINE	EEA	United Kingdom	-4		1.2	18	17	3
ABEROOLINE	Non EEA	Braol	- 4	4	3	3	7	
ABERIOOLINE	Non EEA	Herep			. 2	7	2	
ABEROOLINE	Non EEA	Svitserland		1			1	
ABERGOLINE - SOLUTION FOR INJECTION	BEA .	Audita	4		4	,		1
ABEROOLINE - BOLUTION FOR INJECTION	#EA	Balgium	9	- 14	- 2	1		1
ABEROOLINE - SOLUTION FOR DUBCTION	EEA	Crech Republic	2	2	1	1		
ABEROOLINE - SOLUTION FOR INJECTION	BEA.	Denmark	-41	72	29	61	80	13
ABEROOLINE - DOLUTION FOR INJECTION	EEA .	Estoria			2	27	2	2
ABERGOLINE - SOLUTION FOR INJECTION	624	France	- 24				29	3
ABERGOLINE - SOLUTION FOR INJECTION	BEA	Gernary	22	29	23	32	40	
ABREGOLINE - SOLUTION FOR INJECTION	SEA.	Granie	2	4			3	



What's more, a drop-down menu for Species is included at the very top of this tab, so the user is able to apply this filter, impacting the data displayed both in the map and the table.

5.2.2. Signal detection (with 2 RORs, up to Date 2 and up to Date 1)

In this tab, the user is able to analyse a diverse set of metrics for the product and the period selected, broken down by VedDRA SOC and VedDRA PT levels. The number of cases and number reacted until date 1 and between date 1 and date 2 (period selected), together with ROR calculations are the core of this table.

Moreover, a product hierarchy and species drop-down menus have been included at the top, so the user is able to analyse information from different points of view and for any species for which AERs have been received for a particular product/substance.

- ROR until Date 2: cumulative ROR
- ROR until Date 1: ROR prior to the period selected.

Con rim	al arts, proj	and a first the select	# 1.5173.PT	- Space	(relies	(with	2 8065	op in Date 1.	caliple D	6-2) 0 4: 801 F	-									1
	AND REI	WEEN DATE 1	AND DATE	2				RUNNERO	P CASES	INTEL DATE 1						TOTAL N	IN RO	KUP CAS	25	
nikal Heran de 1: 15042 de 2: 15052	o tevel (Pro Direction)	daar of product short						Product How Date & Mill Date 2 Mill	ente texel 9202 9202 te d 920	Medica el proclast eda 20	1					Product He Delta (2.10) Delta 2.10)	0426 0426 0426	2 2 2 2 3 1 8 1 8 1 8 1 8 1 8 1 8 1 8 1 8 1 8 1	deneri pretat de t	
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10/10/10	Application 204 Approx.	Application sits blatter	3		514	15.2	NF.	1000000	Applice 204 decide	er Agelorden alls bizter			19	- 167	4%			erstrock	roptorben atta buen	
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		Application state intention			14	14.2	44			Application of a break on	1		14	- 14.3	16.12				Application allo Inflammation	
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		Application rade	1		4.14	8.04	< Br			Apple stars whe	9	54	0.54	£./1	0.17				Apple of two sets	
		Applied for site mass 1600	,		64	14.2	14			Application site mass 1800			14	14.2	42				Application allo maccoardient	
		Application atta maccountient	3		14	12.4	88			Application atta muccoamiliant			14	167	44				dogramps Animalistication	



5.2.2.1. IRIS Line listing – List of signals

From the Signal detection dashboard, it is possible to get the List of signals line listing. To get this functionality, we need to access the third tab 'Signal detection (with 2 RORs, up to Date 1 and to Date 2)' and click on the Medicinal Product shortname. Once we click the product, 'List of signals' line listing option will be displayed to be selected.



ex Concrete al and the	special Vertue solid	ALC: NO.	Separal de	(echor	(with	2 80985	op to Bate 1.	and up to Date	N) (SERVICE H	duran /								1
INDER OF CASES DE	TWEEN DATE 1	AND DATE	2				NUMBER	E CASES UN	TTI DATE I						TOTAL NUM	RER OF CAS	ers.	
roduct Hierarchy Level () the 1: 10/04/2020 the 2: 11/05/2020 HI:S4:2 Specker ()2:2	indani padua mar S	hare Y					Product Illes Cate 1: 11/3 Cate 2: 11/3 Species ()	nanchy Level (H 4,7323 5,7323 10:54:55 Dag	eldrei product mor	are v					Product litera Date 1: 11(04) Date 2: 11(02) Species Do	nchy Level <u>14</u> 2003 2003 JD 54 55 9	dictral product dier	Tate ¥
reduned and VedDita	VICTORS FT ENGIN	Number of Longo Estates Cate 1 and	Rambor related betweet data L and	nos. O unil data	100 #10 \$10	5.03. (I)	Medianal product distance	Aro Voltita NOC some	VICTIRA FT CASA	Humber el Leves entil éste	Number roaded and date	NOR. (-) Land	nce well dete	908 (1) #44	Notichel predect A	SOC none	volution of a	Teld marke drawn
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	Application also hearsonnead	6		0.07	9.23	0.67			Application also heximitings	:	3	0.07	0.23	6.72			Application site	1
	Application site has change	:		0.23	9.23	0.45			Application also have change	23	64	0.26	0.29	8.42			Application site	-
	Application site infection	c		34,9	N/S	58A			Application sits in Action	:	2	19.4	N/A	NUA			Application site	
	Application site information	6		0.00	9.27	0.32			Application site in Burnstein	31	11	0.05	0.18	8.33			Application site	
	Application site leave	2	:	0.15	9.2	0.38			Application sits lose e	31	15	0.11	0.23	8.27			Application site mass NOS	
	Application site mete MUS			NA	1(9	- 194			Application site enco MUS	3	2	19.4	M/4	N(A			Application site mecapyrations	
	Application size			N/A	R9	194			Application with		2	19.4	14/4	N(A			discharge Andreating site	



Veterinary Pharmacovigilance EVVET - Data Warehouse user manual

ras tilla	Process (r) pe	Notichel product name	Substance	Pt woldre term	Species	Submitted UN	Delc of exclose	Prioridaation	Proposal for action (PAH)	Regulatory outcome	Substatus	Latest publications
Covera de	Annual stationicity pelonicourt	Example 1300 mg. Choweldo Johini.	Fundance			28/10/2022					Native	26/00/2022
		Indiate and a second se	Puncience			20/00/2322					Colling	20/20/2022
		Branceta 1400 mg - Chowello Jubliol	Purclence			25/10/2022					Colors	28/00/2922
		Brancets 250 mg Chronobic Sobiet.	Flanclance			25/10/2322					"colting	26(10)2322
		Enswects 500 mg - Chevrabia Sobiet	Functioner			25/10/2022					Peaking	26(10) 2022
CARD IN	Signal management sebmission	Enswedts 1000 mg - Chevrebie Sobiet	Functioner	Nepatapathy	Cog	25/10/2022	23/16/2022		Signal is reluted		S.bwitted	26(10)2322
	Spor narajerek alart vekt Alare conenario subreside	Starects 312.5 mg - Chevable sobjet	Funcience	Hepatapathy	Cop	25/10/2022	23/16/2022		Signal is reluted		S.britted	26/10/2022
		Enseeds 1400 reg - Chaveble toblet	Fundance	Hepatopathy	Cop	25/10/2022	23/18/2022		Signal is reluted		S.britted	26(10)2022
		Enseets 250 mg Chevrobie tab et	Flumiener	Hepatopathy .	Cog	25/10/2022	23/10/2022		Signal is retuted		3.by Biel	26(10)2022
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LAND .	tubrelation	Downets 1200 reg - Spot-on relation	Catalane			26/10/2322					POCEDIA	28(10)(2022
		Downets 112.5 mg - Spot-on relation (cets)	Fluxieur			26/10/2022					PEREMA	28(10)2022
		Downets 112,5 mg - Spot-on relation (dogs)	Fusiew			26/10/3323					ACCEVA	38(10)2303
		Bowerts 1400 mg - Spot-on relation	Endere			26/10/2022					PEREMA	28/10/2022
		Bowerts 350 ang - Spar-on Isolation (extr.)	Fluxieur			26/10/2022					ACKENA	28(10)2022
		Bowerts 250 ang - Spar-on solution (dogs)	Fluthaw			26/10/2022					ACCENA	58(10)2022
		Rowerts S30 ang - Span-on relation (cets)	Fluxierer			26/10/2022					ACCEVA	58010(2002
		Reports 500 md - Southers	Eastern			260(0)2022					are the	26/20/2022

Image 61: List of signals line listing from Signal detection dashboard

5.2.3. Static ROR Evaluation

Static ROR is focused on the different inputs for the Reporting Odds Ratio calculation (ROR) as well as the ROR metric itself, including both lower and upper bounds, aka ROR(-) and ROR(+). All the metrics are displayed at VedDRA SOC level, but the user can change the VedDRA level via the VedDRA Output Level prompt.

At the top, same filters as in the Signal detection (with 2 RORs, up to Date 2 and up to Date 1) tab have been included, this is:

- Product Hierarchy Level, giving users the chance to visualise the data by medicinal product
- shortname, reported brand name, active substance, product composition or ATCvet code.
- Species filter so the user can analyse these metrics for every species impacted by the product.
- Reaction filters at the very top, so the user is able to filter at every level. Lastly, the number of animals affected metric is also displayed at VedDRA SOC level.

term (Lata V)								
ummi i Calla V 2								
and maked starting	and include No. onto	Number randool it - Restorie with street	of the parties of - family off stated offer	A section C - Reports - office	studied by all matter D - Second allia	A local and write a local line (C)	11.00	-
04	Balanced discribers			224		1.000	1.00 2.5	æ
	thread and brighten authors described	4	8	248	112	1.110	810 B	80
	Karlonashie sullet Eaches		20.	141	10	2 542	2.0	£
	Equation bast dispetters	5.08	84	204	392	3.340	24	£.
	Rue desiders	4		188	47	2.000	P	Æ
	People-Drary discrimit	5		348		LAIR	6/# . B/P	Æ
	Stature substitutes	15	1.1	16F	183	2.498	Auf A.F	Æ
	Synthysiate	14).	20	348	386	3.342	247 2.7	£Ľ.
	Parmer (and dentes	14	(3)	34	147	2,40	3.4	£
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	Numiniation for tex		10	200		24%	1.4	ε.
	herningce denters	41			24	1.5%	2 M 3.5	е.
	Parar and univery deprints	- A			18	2,649	ALK . 91	£.,
	Parolotic spherident			110	209	3,411		£.,
	Reporting that danders					1.54	10,00	н.
	(Not and appropriate disordery					114	1.77 6.31	£.,
	Rudwine dispidule	478	144	· .3e.	1.349	141	10.0	

Image 62: Static ROR Evaluation

6. Signal evaluation

This dashboard enables the user to evaluate signals using different parameters (age, time to onset, off label use, geographical distribution, pharmaceutical form, other products involved, other VedDRA terms).

It is also focused on finding both associated products and VedDRAs, so the user is able to visualise the main products and reactions related to ones selected in the filters page.



Image 63: Signal evaluation menus

The dashboard is broken down into four tabs: Animal Data, Product Information, Product Association and Associated VedDRA terms, as well as the tab for filtering the query (Filters) and one last tab with a link to VPhS.

At the top of every tab the user will find a header including the usual key figures, being for this dashboard: Number of cases, Animals affected, and Animals died, as follows.

|--|

Image 64: Signal evaluation key figures

6.1. Filters

1. Choose from all attributes in the Product Information (required)

In this prompt you select at what level of the product hierarchy you want to run your query. These levels are:

- Active substance level: Results will be related to AERs for products that contain the selected active substance(s).
- **Product Short name:** Results will be related to AERs for selected product(s) grouped by the product short name.
- **ATCVet code level:** Results will be related to AERs for products that belong to the selected ATCVet code.
- **Reported Brand Name:** Results will be related to AERs for a selected Product Brand Name as reported in the AER verbatim, prior to standardisation.
- **Product Authorisation Number:** Results will be related to AERs for selected product(s) grouped by the product authorisation number stated in the product dictionary.
- **Reported Authorisation Number:** Results will be related to AERs for selected product(s) grouped by the product authorisation number as reported in the AER.

Product composition level (Composition, Strength, Formulation, Pharma Product): Results will be related to AERs for products that are composed solely of the selected active substance(s), active substance(s) + strength(s), Active substance(s) + Pharmaceutical form(s), Active substance(s) Strength + Pharmaceutical form. This enables users to group products based on their composition, regardless of the trade names of the products.

Active substance	Select Value	~
Product short name	Select Value	~
ATC vet code	Select Value	~
Reported brand name	Select Value	~
Product authorisation number	Select Value	~
Reported authorisation number	Select Value	~
Product composition (Type = Composition)	Select Value	~
Product composition (Type = Strength)	Select Value	~
Product composition (Type = Formulation)	Select Value	~
Product composition (Type = Pharma Product)	Select Value	~

Image 65: Filter options

2. Message received date range (required)

In this prompt you select a range of dates.

message received oate range (kequired)		
Message received date Between 03/08/2021	3/09/2021	ß

Image 66: Message received date range

3. Report filter (required)

Select whether your result should contain only **animal** or **human** AERs by ticking the relevant option, or both by selecting both Animal and Human.



Image 67: Report filter

4. VedDRA hierarchy

In this prompt you select one or multiple VedDRA terms at different levels. By informing the left column of VedDRA terms, we can filter by one or multiple terms. When selecting only one term in each level, the query will return all cases where the VedDRA Terms selected have been reported simultaneously (AND). When using the drop-down menus both from the left and the right side, we will get all cases where at least one of the VedDRA terms informed has been reported (OR). In both sides, if more than one term is selected in the same level, the query will return all cases where at least one of the VedDRA terms (OR).

	VedDRA Term SOCSelect Value	×		VoiDRA Tam SOC	Select Wate-	¥
	VedDRA Term HETGelect Value	*	OR	VedDRA Terrs HLT	-Select Value-	•
	VINDRA TANK PT SHART WALK-	*		VedDRA Term FT	-Select Value-	×
	vedbick term (L) -Sidext Value -	M		Velota ten tul	Select Water	×
"Use the drop down o	n the left side in filter by one or multiple VeCDA	d terms, 10hen selecting	r only one berry in each level, the query will	return all cases where the 1400004 Te	and selected ha	ve been reported standbareous

Image 68: VedDRA hierarchy

5. All cases or new cases (required)

In this prompt you have to must select one of the two options, being "All Cases" selected by default. Selecting "New cases" will return data related only to new reports received in EVVET during the selected period, and period and the selected period will exclude from the data set follow ups to reports initially received in EVVET prior to the selected period.



Image 69: All cases or new cases

6. Choose from list of optional AE Report filters

No answer is required for this prompt. By applying any of these filters the results dataset will be restricted to AERs that meet the selected conditions.

Age (hours) >=	Select Value	- 9	Gender	Select Velue	Y	Original re	ceived date Between	- EB	Es
<-	Select Value		Species	Select Value	• s	tart date of rea	ction/event Between	(B-	6
Age (days) >=	Select Value		Breed	Select Value	~	Authorisation	n procedureSelect Value		~
<-	Select Value		Occurrence region	Select Value	~	Infor	mation typeSelect Value		
Age (months) >=	Select Value		Occurrence country	Select Value	Prie	mary source ca	tegorisationSelect Value		
<=	Select Value		Organisation	Select Value	*	Is use accord	ling to labelSelect Value		1
Age (years) >=	Select Value		Report type	Select Value	•	Exclude lac	k of efficacy 🗆 Yes		
<=	Select Value				,	Hide known Ver	dDRA terms DYes		
Is off label									
Indication O Yes		Produc	t expired Vex	5	torage	□ Yes □ No	Treatment View	Other issue	Yes No
Overdosed O Yes		Route	of admin U Yes	Species	target	□ Yes	Underdosed O Yes		



- **Original Received Date**: The date that the MAH or NCA first received the message.
- Serious: The system will return only the serious or the non-serious reports.
- **Information type vs Exclude lack of efficacy:** If you want to exclude the lack of efficacy cases and you exclude "Lack of efficacy" within the Information type drop-down menu (by including all other information types), you will get the reports where LOE has been reported together with other issues/information types. However, if you tick the box "Yes" in "Exclude lack of efficacy", the system will exclude those reports where the VedDRA term "Lack of efficacy" has been reported.

7. Threshold ROR (required)

This prompt is mandatory but filled by default with ROR >= 2, ROR(-) >= 1 and Number of cases >= 3. The user is able to customize these values for the purpose of the analysis.

$ROR \ge = 2$	ROR (-) >= 1	Number of cases >= 3

Image 71:Threshold ROR

8. Historical data

No answer is required for this prompt. By default, a snapshot of the day will be set. If a different date is selected, the results will reflect the data in EVVET as per the date selected, excluding data received after the selected date.

Snapshot from 15/09/2021		60
	R	eset ~

Image 72: Historical data
6.2. Animal data

The charts displayed in the Animal data tab from top to bottom are as follows:

- Number of cases time to onset: the pie chart shows the number of cases by time to onset for the product and period specified in thefilters page. Time to onset goes from <=2 minutes to >30 days.
- Number of animals affected and died over years (LAST 10 YEARS): the bar chart shows the number of animals affected and died over the last 10 years, so it is not limited by the period specified in the filters page. Product selected applies. Red bars show thenumber of animals died and blue bars the number of animals affected.



Image 73: Animal data charts

Below this second chart, the user will find a switch to table functionality so the information can be shown either as a chart or a classic table format.

Message received year	Number of animals affected	Number of animals died
2016	273	61
2017	11	4
2018	129	38
2019	17	3
2020	5	2

Image 74: Animai data cumulative viev	Image	74:	Animal	data	cumulative	view
---------------------------------------	-------	-----	--------	------	------------	------

- **Number of cases by species:** the bar chart shows the number of cases by species for the product and period specified in the filterspage.
- **Number of cases by species and off-label use:** the heat map chart shows the number of cases by species together with the off-label use information, broken down into YES/NO/NO DATA.



Image 75: Number of cases by species and off label use charts

Below this second chart, the user will find a switch to table functionality so the information can be shown both as a chart or a classic table format.

Is use according to label	Yes	No	No Data	Number of cases
	Number of cases	Number of cases	Number of cases	
Species △▽				
Cattle	265	19	49	333
Grand Total	265	19	49	333

Image 76: Number of cases by species and off label use table

6.3. Product information

The charts displayed in the Product information tab from top to bottom are as follows:

- Number of animals affected/died by country: the map shows the number of animals affected/died by country for the product and period specified in the filters page. The darker the blue, the more cases associated with a specific country. A drop-down menu has also been included at the top in order to jump from animals affected to animals died. In addition, a link has been added at the bottom so the user can visualise in table format the Number of animals affected by pharmaceutical form or active substance.
- **Number of cases by country and species:** the bar chart shows the number of cases by country and species for the product and period specified in the filters page. Blue bars show the number of cases, orange bars show the number of animals affected and green bars show the number of animals died. Moreover, a Switch to table link at the bottom has been included so the user is able to display this same information in table format.





				Pharmaceutical product	t form 🛩			
Species Cattle V		Information type	Doth safety and	lack of expected effectiveness				
harmaceutical product	0	0	Animal	Animal	Animal	Number of AERs	Number of animals affected	Number of animals died
orm	Occurrence region	Occurrence country (0)	Number of ADIts	Number of animals affected	Number of animals died			
OLUTION FOR INSECTION	EEA.	ALISTECA	1	3	0	1	3	
OLUTION FOR INJECTION	EEA	BELGUIN	1	1	0	1	1	
OLUTION FOR INJECTION	EEA	DENMARK	7	21	0	7	21	
OLUTION FOR INSECTION	EEA	FRANCE	3	3	1	3	3	
OLUTION FOR INJECTION	EEA	GERMANY	3	3	2	3	3	
OLUTION FOR INJECTION	EEA	NETHERLANDS	2	2	2	2	2	
OLUTION FOR INJECTION	EEA	SPAIN	1	1	0	1	1	
OUTTON FOR INTERTION	Non FEA	69470						

Image 78: Number of animals affected by pharmaceutical form or active substance

Medicinal product	shortname VELA	CTIS Occurrence region	n EEA 🔽 Species	Cattle
Occurrence country	Number of cases	Number of animals affected	Number of animals died	
Austria	5	7	2	
Belgium	6	11	5	
Czech Republic	1	2	0	
Denmark	81	116	28	
France	43	45	11	
Germany	65	75	20	
Greece	1	3	0	
Hungary	16	16	10	
Italy	11	20	1	
Netherlands	32	37	11	
Poland	3	4	0	
5pain	27	36	10	
United Kingdom	12	14	2	

Image 79: Number of cases by country and species

• **Number of cases by information type:** the pie chart shows the number of cases by information type for the product and period specified in the filters page.

A couple of interdependent drop-down menus have been included at the top, so the user is able to see the information as Medicinal product short name, Reported brand name, Product composition, Active substance or ATCvet code and broken-down consequently.

• Number of cases over year (LAST 10 YEAR): The bar chart shows the number of cases over the year for the last 10-year span, not applying the message received dates included in the filters page. Blue bars show the number of cases, and the orange line shows the cumulative number of cases.

On top of that, two interdependent drop-down menus have been included so the user is able to see the information such as Medicinal product short name, Reported brand name, Product composition, Active substance or ATCvet code as well as display it by information type.



Image 80: Number of cases over year (LAST 10 YEARS) chart

6.4. Product association

The charts displayed in the Product association tab from top to bottom are as follows:

- Number of cases by product used in association with others: The tree map shows the
 number of cases by product used in association with others displayed as hierarchical data, so the
 user is able to see the concomitant products used together with the product selected in the filters
 page. The darker the blue, the higher the number of cases for the combination of products. Also,
 every rectangle has an area proportional to the number of cases.
- Number of cases by species: Horizontal bar chart. Interconnected to the tree map, in this chart, the user can see the number of cases by species for the concomitant products to the main product selected in the filters page. These products have to be selected in the drop-down menu enabled at the top for that purpose.

Number of cases by species: Heat map. Also interconnected to the tree map, in this heatmap the user can see the number of cases by species for the concomitant products related to the main product selected in the filters page, including also the reactions at VedDRA level.



Image 81: Number of cases by species

6.4.1. Cases with no other products reported

Additionally, two links have been enabled at the right side for the user to access to the detailed tablesfor cases without other products reported.

Species Cattle 🗸							
Medicinal product shortname	VedDRA SOC name	VedDRA PT name	Number of cases	Reaction count	ROR (-)	ROR	ROR (+)
DRAXOUN	Application site disorders	Injection site hair change	1	1	N/A	N/A	N/A
DRAXXIN	Application site disorders	Injection site necrosis	1	1	N/A	N/A	N/A
DRAXXIN	Application site disorders	Injection site pain	1	1	N/A	N/A	N/A

Image 82: Cases with no other products reported

6.4.2. Cases with other product reported

And with other products reported.

urrent product									
				International Social	CH Y				
		nerim Calife V							
	10. 1	eiene preketsnetwere	indial states have	her ef cases for the pro	mart (COD ()) for the	NOR in the post of 505.(1)	to-the		
	45	16035	application site deprétere		14 1.0	2.5	2400		
ssociated products			United and						
			-4022.042.742	CON PERSONAL PROPERTY.	A.A. THERE AND ADDRESS				
Speries (Patter V)									
Speries (<u>Catta V)</u> edicial podut d'ordane	Autorited induced public	radDRA SOC rame	Number of cases for the comb	Nation disalian	hundes of animals effected	turden of some (total	com (+) fan skur protosetion	KOK for the combination KOK (+) for the	e cororat
Nyrreins (<u>Partia V.)</u> Nedoral protust alforitaria 200001	Associated endanced product and	nadolisk sold name koji calcer alte clamfere	Number of cases for the comb	nation count t	Sunder of animals affected 10	haden of some (total Male	can (+) far dur andraetica ta	ADR. for the combination IRDR (+) for the	e cororat M

Image 83: Cases with other product reported

6.5. Associated VedDRA

The last tab of the Signal Evaluation dashboard is related to the reactions associated with the one selected in the filters page. A table like the one below will show up, displaying the VedDRA SOCs linked to the VedDRA term(s) previously set.

In addition to that, a VedDRA SOC drop-down menu has been included at the top in case the user selects more than one term. Right below, a couple of drop-down menus allow the user to jump from Medicinal short name to ATCVet code or active substance-based analysis, as well as associated VedDRA terms displayed at a different level.

				24	NEN STOC - ONE - ANDIN	el vitale pas 💌	_				
and venues											
				Nedora pob.		Marter 200 KALIER BORD					
Antin Gali- M											
Kindulaci producti rophicnar	hadown sociation	American Straffers Straffers	Aradox and	Burrian scart hold in the read-readers	Number of servers	Send Manders at serves (Med 200)	ASK (r) has the remains that	surface	he participant of the 1-1 fb	de coloration dender al.	atroli .
COLOCK .	Application also discrite	an Estavia al dancere		1	15	1	12	812	45	164	
		and King and a price distriction		1	12	4	14	B TA	- A	18.4	
D-9K/R/A	Application are depicted	A PORTAL SECONDARY									
DOMONA DOMONA	Application are depicte Application are depicted	na Ergeline successions na Ergelinen		1	Le .	1	14	10.0	12. m	78.4	104
000000 000000 000000	Application and depth Replication due deer de Replication die disarder	ra Ermigders 15 Brechtersfeldsterter		1	14	1	12	80.5	22	98.5	
DOUGA DOUGA DOUGA	Application are deep to Replacitor rate deep to Replacitor dis deep to Replacitor are deep to	re braniguians re braniguians re Monsterio relatabanten re indens, cierdes		;	14	1	10 10	605 812		965 965	1

Image 84: Associated VedDRA

As usual, the Number of cases column includes access to the second-level reports (See <u>3.2.1. See</u> <u>Details</u>).

6.6. Link to VPhS

Pending to be updated with a link to IRIS. Adverse events comparison between 2 periods. This dashboard allows users to compare data for two time periods based on three key dates:

- Message received date
- Original received date
- Date of onset

And three performance indicators:

- Number of cases
- ROR
- ROR(-)

Consequently, for the periods selected and date selected, the user will get the number of cases and ROR metrics for both the period 1 and the period 2 in the same chart so it can be quickly compared. The dashboard is broken in two tabs: one for the filters and the other for the actual charts:



Image 85: Adverse events comparison between 2 periods menu

6.7. Filters

1. Choose from all attributes in the Product Information (required)

In this prompt the user selects at what level of the product hierarchy you want to run your query. These levels are:

- Active substance level: results will be related to AERs for products that contain the selected active substance(s).
- **Product Short name:** results will be related to AERs for selected product(s) grouped by the product short name.
- **ATCVet code level:** results will be related to AERs for products that belong to the selected ATCVet code.
- **Reported Brand Name:** results will be related to AERs for a selected Product Brand Name as reported in the AER verbatim, prior to standardisation.
- **Product Authorisation Number: r**esults will be related to AERs for selected product(s) grouped by the product authorisation number stated in the product dictionary.
- **Reported Authorisation Number:** results will be related to AERs for selected product(s) grouped by the product authorisation number as reported in the AER.
- Product composition level (Composition, Strength, Formulation, Pharma Product): results will be related to AERs for products that are composed solely of the selected active substance(s), active substance(s) + strength(s), Active substance(s) + Pharmaceutical form(s), Active substance(s) Strength + Pharmaceutical form. This enables users to group products based on their composition, regardless of the trade names of the products.

Active substance	Select Value	~
Product short name	Select Value	~
ATC vet code	Select Value	~
Reported brand name	Select Value	~
Product authorisation number	Select Value	~
Reported authorisation number	Select Value	~
Product composition (Type = Composition)	Select Value	~
Product composition (Type = Strength)	Select Value	~
Product composition (Type = Formulation)	Select Value	~
Product composition (Type = Pharma Product)	Select Value	~

Image 86: Filter options

2. Time periods (required)

In this prompt the user sets the different time periods likely to be compared for the 3 indicators included in the dashboard: Message received date, Original received date and Date of onset.

Select first time period to compare	re		Select second time period to com	pare	
Hestage received date Between	05-	60	Henry received date between	16-	65
Organal received date Debusan	66-	65	Original received date Debasers	06-	66
fade of arrest Debreen	10-	05	Entry of second Datasan	0b-	60

Image 87: Time periods

3. Report filter (required)

Select whether your result should contain only **animal** or **human** AERs by ticking the relevant option, or both by selecting both Animal and Human.





4. All cases or new cases (required)

In this prompt you have to select one of the two options, being "All Cases" selected by default. Selecting "New cases" will return data related only to new reports received in EVVET during the selected period and will exclude from the data set follow ups to reports initially received in EVVET prior to the selected period.



Image 89: all cases or new cases

5. Choose from list of optional AE Report filters

No answer is required for this prompt. By applying any of these filters the results dataset will be restricted to AERs that meet the selected conditions.

Age (hours) >=Select Valu	e 🗹 🛛 Gende	rSelect Value 💌	Authorisation procedure	Select Value		*
<= Select Valu	e 💌 Specie	sSelect Value 💌	Information type	Select Value		~
Age (days) >=Select Valu	e 🗹 Dreed	jSelect Value 💌	Primary source categorisation	Select Value		*
-Select Value	e 💌 Occurrence region	Select Value 💌	Is use according to label	Select Value		*
Age (months) >=Select Valu	e 💌 Occurrence country	Select Value 💌	Exclude lack of efficacy	○Yes		
<=Select Valu	e 🗹 Organisation	Select Value 💌	Hide known VedDRA terms	□ Yes		
Age (years) >=Select Valu	e 💌 Report type	🛛 Select Value 💌				
c=Select Valu	e 💌					
Is off label						
Indication Ves	Product expired Ves	Sto	rage 🗆 Yes Tre	atment 🗆 Yes	Other issue Ves	
No	O No		No	□ No	D No	

Image 90: Optional AE Report filters

- Original Received Date: date that the MAH or NCA first received the message.
- **Serious**: the system will return only the serious or the non-serious reports.
- Information type vs Exclude lack of efficacy: If you want to exclude the lack of efficacy cases and you exclude "Lack of efficacy" within the Information type drop-down menu (by including all other information types), you will get the reports where LOE has been reported together with other issues/information types. However, if you tick the box "Yes" in "Exclude lack of efficacy", the system will exclude those reports where the VedDRA term "Lack of efficacy" has been reported.

6. Threshold ROR (required)

This prompt is mandatory but filled by default with ROR >= 2, ROR(-) >= 1 and Number of cases >= 3. The user is able to customize these values for the purpose of the analysis.

ROR (-) >= 1	Number of cases >= 3	
	ROR (-) >= 1	ROR (-) >= 1 Number of cases >= 3

Image 91: Threshold ROR

7. Historical data

No answer is required for this prompt. By default, a snapshot of the day will be set. If a different date is selected, the results will reflect the data in EVVET as per the selected date, excluding data received after the selected date.

Snapshot from 21/09/2021	0	
	Renet *	

Image 92: Historical data

7. Adverse events comparison between 2 periods

After setting the time periods and the rest of required fields within the filters page, the user clicks on the "Adverse events comparison between 2 periods" tab to visualise the dashboard.

The first functionality the user is going to see is the radio buttons, at the very top. Using those, the user will be able to jump from one indicator to the others for the selected time period, which will be always stated right below.

Message received dat	e Original received date Date of onset
Perio	d 1: 2012-09-20 - 2015-09-20
Perio	d 2: 2015-09-20 - 2018-09-20

Image 93: Adverse events comparison between 2 periods date criteria

Apart from that, the user will visualise the 3 main elements included in the dashboard: the horizontal bar charts representing the following KPIs: Number of cases, ROR and ROR (-).

On top of every one of them, several drop-down menus have been included in order to:

- Visualise the charts by product, reported brand name, product composition, active substance or ATCvet code
- Jump from one VedDRA level to the others.
- Select all the species involved with this product and time periods.
- Jump between the products selected in the filters page.



Image 94: Adverse events comparison between 2 periods dashboard

Additionally, two heatmaps in the bottom display the number of cases for the product and period selected, one for the Period 1 and another for the Period 2, optional filter for species not applicable.





The heatmap can be visualised by product, reported brand name, product composition, active substance or ATCvet using the drop-down menus on top. After selecting the type of visualisation, the drop-down menus set right below will display a list accordingly.

7.1.1. Message received date – See details

At the very bottom of the dashboard, a link has been enabled for the user to navigate to the See details tables, and depending on the radio button selected this will display on date or the others.



Image 96: Message received date – See details

By clicking this link, the user will open the table in a different tab, with the following information.

7.1.2. Original received date - See details

Same for the Original received date.

```
Predoval product shortname Ve
Namen: Alpane Ve
Namen: Alpane Vetat Society Predo 1: Norther of cases Field 1: North () Predo 1: NOR (+) Predo 1: NOR (+) Predo 2: Norther of cases Field 2: Norther of c
```

Image 97: Original received date - See details

7.1.3. Date of onset - See details

Same for the Date of onset.

8. Data stratification

This dashboard allows users to find products involved in a particular reaction or group of reactions by displaying the number of cases for that pre-set conditions (**Adverse events by VedDRA terms**). Additionally, using the second tab (Product stratification) the user can check the ROR for the product or group of products at all VedDRA levels, including or excluding a second product from the equation, as well as the Number of animals affected divided by species at VedDRA SOC level.

On all other dashboards, the ROR is calculated by comparing the number of cases for the selected product/substance to "all other products" in the EVVET database.

This dashboard aims to allow the user to exclude outliers or simply narrow the ROR for comparison purposes. The data stratification dashboard is divided in 3 tabs:





8.1. Filters

1. Product information (required for product stratification)

The first prompt is product-oriented, and the user must fill it in to get an overview of the Product stratification tab. For that purpose and depending on the analysis, the user will check "Compared to" or "Compared to all except".

The user should select the product/substance subject to their evaluation on the left side. For instance, selecting "Compared to" and an ATCvet code on the filter on the right side will restrict the denominator of the ROR to products belonging to the selected ATCvet code.

Selecting "Compared to all except", and a product or substance on the left side will exclude the selected product/substance from the denominator of the ROR.

Active substance,Indext Value	10		Act up substance, -tooler, Walker-	*
Protect shart neme interfect values.	IN.		Notici shed - braid back to be	
Will per code	i		Allbruer code - Salact Velue	1
Reported brand name when when-	ie.		Apported brand hansetwiley' table-	1961
Product collegence on marching Solicit Viria	2	() Garyand Ta	Product authorization manage - School Velue	
Reported authorized on number Solicit Virus	10	Concerned To M Parage	Awaneted Australiantian number - Soloci Welus	
volut toregounce (Trac = Coreputor) -telect causes	Let		Fraduct companyion (Trac + Companyion) -delect Value-	(M)
Preduct composition (Page + Strandb) Schot Value	(R. 1		Protect component (Type + Strength) Solot: Velue	3
Endust composition (lyps - ("presidence)tenlert velue	le:		#roduct compatition (f):pe (formulation)tudent tal.e	19
act concost in (Troc + Phanes Contact)Gelect Chila	19		Product, compared and (Trace = Pharmar Notand),Gellect Value	1

Image 99: Product information filters

2. VedDRA terms (required for adverse events by VedDRA terms)

The second prompt is related to AE reactions and the user must fill it in to get an overview of the Adverse events by VedDRA terms tab. For that purpose and depending on the analysis, the user will check "AND" or "AND NOT".

NA Deritis (Amplebred for advecte reveals by VellovA Deritis)		
Valter for and Set take		Welder Turn Boo Seed Wike
Vertilik Terrelik T. Select Velue	0.445	Hardfills Terre III.T Select Value
VerDisk Term FT - Helical Value - M	O AND MOR	VerDNA Term ET Helical Valuers M
ValDO Incide Taken		Weiden terrettat weisen Weisen

Image 100: VedDRA terms filter

3. Animal information (required)



Image 101: Animal information filter

4. All cases or new cases (required)

In this prompt you have to select one of the two options, being "All Cases" selected by default. Selecting "New cases" will return data related only to new reports received in EVVET during the selected period and will exclude from the data set follow ups to reports initially received in EVVET prior to the selected period.



Image 102: All cases or new cases filter

5. Choose from list of optional AE Report filters

No answer is required for this prompt. By applying any of these filters the results dataset will be restricted to AERs that meet the selected conditions.

Age (hours) >=Select Value 💌	GenderSelect Value	Message rec	eived date Between	63-	65
<= - Select Value 💽	Species Select Value	🛛 🗹 🖸 Original rec	eived date Batwaan	B-	63
Age (days) >=Select Value- 😿	BreedSelect Value	🗠 💽 Start date of rear	tion/event Between	13-	13
<=Select Value 💌	Occurrence region Select Value	Authorisation	procedureSelect Value		
Age (months) >= -Select Value-	Occurrence countrySelect Value	🖌 Inform	ation typeSelect Value		4
e =Select Value 💌	OrganisationSelect Value	🗹 Primary source cat	egorisation Select Value		~
Age (years) >=Select Value 💌	Report typeSelect Value	🐱 Is use accord	ng to label Select Value		~
anSelect Value 💌	SeriousSelect Value	🗭 Exclude lack Hide known Ved	of efficacy DYes DRA terms DYes		
Is off label					
Indication 🗆 Yes Produ	ct expired 🗆 Yes 🗌 No	Storage DYes DNo	Treatment C Yes	Other issue 🖸 Yes 🗌 No	
Overdoaed 🗆 Yes Route	of admin 🗆 Yes 🛛 Spo	oes target 🗆 Yes	Underdosed C Yes		

Image 103: Optional AE Report filters

- **Original Received Date:** date that the MAH or NCA first received the message.
- **Serious:** system will return only the serious or the non-serious reports.
- Information type vs Exclude lack of efficacy: if you want to exclude the lack of efficacy cases and you exclude "Lack of efficacy" within the Information type drop-down menu (by including all other information types), you will get the reports where LOE has been reported together with other issues/information types. However, if you tick the box "Yes" in "Exclude lack of efficacy", the system will exclude those reports where the VedDRA term "Lack of efficacy" has been reported.

6. Product MAH filter

By using 'Product MAH filter', it is possible to filter by one specific MAH, so the output of the query will only be data related to the informed MAH (its products)



Image 104: Product MAH filter

7. Threshold ROR (Required)

This prompt is mandatory but filled by default with ROR>=2, ROR(-)>=1 and Number of cases>=3. The user is able to customize these values for the purpose of the analysis.

ROR >= 2	ROR (-) >= 1	Number of cases >= 3

Image 105: Threshold ROR

8. Historical data

No answer is required for this prompt. By default, a snapshot of the day will be set. If a different date is selected, the results will reflect the data in EVVET as per selected date, excluding data received after the selected date.

Snapshot from	21/09/2021	Ē	
		Reset -	

Image 106: Historical data

8.2. Adverse events by VedDRA terms

Filling prompt number 2 is required to visualise this tab. At the top of every tab the user will find a header including the usual key figures, being for thisdashboard: Number of cases, Product count and Animals affected, as follows:



Image 107: Adverse events by VedDRA terms key figures

Right below the header, two charts will display the Top 15 (15 products or less will be listed) of the products associated with the reactions set at the filters page. First chart shows products associated with the first product and second chart shows:

- Products associated with the combination of VedDRAs if the user selects "AND".
- Products associated with the first VedDRA selected and excluding the second from the equation if the user selects "AND NOT".



Image 108:Adverse events by VedDRA terms top 15

Product filters do not apply in this report.

Above the charts, two drop-down menus have been included, one for selecting the different VedDRA terms at SOC level (in case the user selects more than one) and the other for changing from one species to the others.

8.3. Product stratification

Filling prompt number 1 is required to visualise this tab.

Right below the header (see 7.2 Adverse events by VedDRA terms) 2 charts will display with the Top 15 (15 products or less will be listed) of reactions at VedDRA SOC level by ROR.

The first chart shows the ROR for the reactions (at SOC level) related with the first product selected and the second chart will show:

• ROR for the reactions (at SOC level) related to the product selected in the left prompt compared to other products **but** the product selected in the right prompt if "compared to all except" was selected.

Or

• ROR for the reactions (at SOC level) related to the product selected in the left prompt compared all other products belonging to the selected ATCvet code if "Compared to" was selected.



Image 109:Product stratification top 15

Above the charts, four drop-down menus have been included:

- For jumping between VedDRA levels.
- For jumping between Species.
- A product hierarchy level so the user will be able to display the chart by medicinal product short name, reported brand name, product composition, active substance or ATCvet code...
- A drop-down menu interconnected with the previous, displaying the selected product or active substance depending on the level selected on the product hierarchy above.

Another chart is included in this tab, a heatmap, showing the Number of animals affected by VedDRA, SOC terms and ATCvet code. The different blues indicate if that Species- SOC combination belongs to the first, second, third or fourth quartile.



Image 110: Number of animals affected by VedDRA SOC and ATCvet code

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On top of this the user will see a couple of drop-down menus, one for navigating between products (in case more than one is selected) and the other enabled to pick between the ATCvet codess involved.

8.3.1. See details

The "see details" table is only relevant and becomes enabled when the user has selected an ATCvet code for the "Compared to" option on the filters page. (See 3.2.1. See Details).

9. Signalling for reactions linked to a product or ingredient

9.1. Filters

1. Output level (required)

The user must select one of the output levels.

0.1-11		
Output le	Active substance	
	O ATC vet code	

Image 111: Output level

2. Message received date range (required)

In this prompt you select a range of dates.



Image 112: Message received date range

3. Report filter (required)

Select whether your result should contain only **animal** or **human** AERs by ticking the relevant option, or both by selecting both Animal and Human.

s. Repo	rt filter (Required)
	Human or animal O Animal O Human

Image 113: Report filter (human or animal)

4. Product information

The user is required to select either the product MAH or the product authorisation country to enable the signalling for reactions tab.



5. Optional report filters

No answer is required for this prompt. By applying any of these filters the results dataset will be restricted to AERs that meet the selected conditions.

Age (hours) 5 =Select Value 😪	GenderSelect Value 💌	Original received date Batwaan	B-	125
👡 – Select Value – 🐱	Species Solact Value 💌	Start date of reaction/event Between	40-	13
Age (days) >=Select Value 😪	BreedSelect Value 🔽	Authorisation procedure Select Value		
🥿Select Value 💌	Occurrence region Select Value 💌	Information typeSelect Value		Y
Age (months) >= -Select Value 😪	Occurrence countrySelect Value	Primary source categorisationSelect Value		
🖉 Select Value 😿	OrganisationSelect Value 🔽	Is use according to labelSelect Value		
Age (years) >=Select Value 🐱	Report type Select Value 💌	Exclude lack of efficacy Cityes		
e = - Select Value - 🐱	Serious Select Value 🐱	filde known VedDRA terms C Yes		

Image 115: Optional report filters

6. Threshold ROR

This prompt is mandatory but filled by default with ROR>=2, ROR(-)>=1 and Number of cases>=3. The user is able to customize these values for the purpose of the analysis.

Threshold ROR (Require	J)		
ROR >= 2	ROR (-) >= 1	Number of cases >= 3	

Image 116: Threshold ROR

9.2. Signalling for reactions linked to a product or ingredient

In this dashboard the user can see the Top 15 products/active substances/ATCvet codes by number ofcases between date 1 and date 2. ROR and ROR(-) are also included in the visualisation.



Image 117: Top 15 products/active substances/ATCvet codes by number of cases between date 1 and date

At the top the user will be able to jump between the species and reactions (at PT level) for the period and product information selected in the filters page.

9.2.1. See details

Link included at the bottom (See 4.2.1. See Details).

10. Line listing

The line listing dashboard is actually a two tabs line listing, the first tab being focused on the medicinal hierarchy, second tab on the occurrence country/occurrence region.



Image 118: Line listing menu

10.1. Filters

1. Choose from all attributes in the Product Information (required)

In this prompt the user selects at what level of the product hierarchy you want to run your query. These levels are:

- Active substance level: results will be related to AERs for products that contain the selected active substance(s).
- **Product Short name:** Results will be related to AERs for selected product(s) grouped by the product short name.

- **ATCVet code leve**: results will be related to AERs for products that belong to the selected ATCVet code.
- **Reported Brand Name:** results will be related to AERs for a selected Product Brand Name as reported in the AER verbatim, prior to standardisation.
- **Product Authorisation Number:** results will be related to AERs for selected product(s) grouped by the product authorisation number stated in the product dictionary.
- **Reported Authorisation Number:** results will be related to AERs for selected product(s) grouped by the product authorisation number as reported in the AER.
- Product composition level (Composition, Strength, Formulation, Pharma Product): Results will be related to AERs for products that are composed solely of the selected active substance(s), active substance(s) + strength(s), Active substance(s) + Pharmaceutical form(s), Active substance(s) Strength + Pharmaceutical form. This enables users to group products based on their composition, regardless of the trade names of the products.

luct information (Required)		
Active substance	Select Value	•
Product short name	DRAXXIN	-
ATC vet code	Select Value	~
Reported brand name	Select Value	~
Product authorisation number	Select Value	~
Reported authorisation number	Select Value	~
Product composition (Type - Composition)	Select Value	~
Product composition (Type = Strength)	Select Value	~
Product composition (Type = Formulation)	Select Value	~
Product composition (Type = Pharma Product)	Select Value	~

Image 119: Product information filters

2. Report filter (required)

Select whether your result should contain only animal or human AERs by ticking the relevant option, or both by selecting both Animal and Human.



Image 120: Report filter (animal or human)

3. Product MAH filter

The user is required to select either the product MAH or the product authorisation country.



Image 121: Product MAH filter

4. Country filter (required)

The user is required to select either the occurrence region or the country.



Image 122: Country filter

5. Optional report filters

No answer is required for this prompt. By applying any of these filters the results dataset will be restricted to AERs that meet the selected conditions.

Age (hours) >=Select Value Select Value	Gender	Select Value V	Message received date	Between	10-	B
<= ··Select Value - 5	Species	Select Value	Original received date	Between	B-	3
Age (days) >=Select Value	 Breed 	Select Value 🔽	Start date of reaction/event	Between	B-	30
d =Select Value	Organisation	Select Value 🙀	Authorisation procedure	Select Value		~
Age (months) >Select Value -	Report type	Select Value	Information type	Select Value		
<=Select Value-	Serious	Select Value 💽	Primary source categorisation	Select Value		-
Age (years) >=Select Value	1		Is use according to label	Select Value		~
diaSelect Value	e .		Exclude lack of efficacy Hide known VedDRA terms	□ Yes □ Yes		
Is off label						
Indication Yes Proc	luct expired C Y	les Jo	Storage CYes	Treatment 🗍 Yes	Other issue) Yes No
Overdosed Ves Rou	ite of admin 🖂 Y	les Sp	ecies target OYes	Underdosed OYes		

Image 123: Optional report filters

10.2. Line listing by medicinal hierarchy – overview of main AER information

After filling in the mandatory fields, the user clicks on the first tab and navigates to the line listing dashboard, with the usual second level's line listing report structure.

The line listing is the most detailed table the user has access to, basically with the full information about a case.

In the dashboard, though, a couple of drop-down menus have been included at the top. In regards of this first tab, the user will be able to select a product hierarchy (Medicinal product short name, reported brand name, product composition, active substance, ATCVet code) and then another interconnected drop-down menu to jump from one product, substance, etc. to the others.



Image 124: Line listing by medicinal hierarchy – Overview of main AER information

10.3. Line listing by country – Overview of main AER information

In regards of the second tab, the user will be able to select between occurrence region or country, and then another interconnected drop-down menu to jump from one region or country to the others.



Image 125: Line listing by country – Overview of main AER information

11. List of products

11.1. Filters

1. Choose from all attributes in the product information (required)

In this prompt the user selects at what level of the product hierarchy you want to run your query. These levels are:

- Active substance level: results will be related to AERs for products that contain the selected active substance(s).
- **Product short name:** results will be related to AERs for selected product(s) grouped by the product short name.
- **ATCVet code level:** results will be related to AERs for products that belong to the selected ATC Vet Code.
- **Reported Brand Name:** results will be related to AERs for a selected product brand name as reported in the AER verbatim, prior to standardisation.
- **Product authorisation number:** results will be related to AERs for selected product(s) grouped by the product authorisation number stated in the product dictionary.
- **Reported authorisation number:** results will be related to AERs for selected product(s) grouped by the product authorisation number as reported in the AER.
- Product composition level (Composition, Strength, Formulation, Pharma Product): results will be related to AERs for products that are composed solely of the selected active substance(s), active substance(s) + strength(s), Active substance(s) + Pharmaceutical form(s), Active substance(s) Strength + Pharmaceutical form. This enables users to group products based on their composition, regardless of the trade names of the products.

Active substance	Select Value	~
Product short name	Select Value	~
ATC vet code	Select Value	~
Product authorisation number	Select Value	
Product composition (Type = Composition)	Select Value	
Product composition (Type = Strength)	Select Value	-
Product composition (Type = Formulation)	Select Value	4
Product composition (Type - Pharma Product)	Select Value	-

Image 126: Product Information filters

2. Optional report filters

No answer is required for this prompt. By applying any of these filters the results dataset will be restricted to AERs that meet the selected conditions.

	Calact Malus	
Product authorisation procedure	Select Value 💌	
Product authorisation country	Select Value 👻	
Product MAN	Select Value 💌	
Product species	Select Value 🐼	

Image 127: Optional report filters

11.2. List of products

This dashboard displays several charts representing Number of cases metrics for the product or products selected in the filters page. At the top the user will find a header including the usual key figures, for this dashboard: Number of cases, Number of AERs and Fatal cases, as follows:



Image 128: List of products key figures

The first set of charts shows two pie charts with the number of cases by active substance and by medicinal product short name:

ander of reserve office a director	Landar of cause by markelout pool of shorten as
Landra Landra	No Contraction of the second s

Image 129: Number of cases by active substance and by medicinal product short name

Second set of charts includes three pie charts with number of cases by ATCvet code, pharmaceutical form and authorisation procedure:



Image 130: Number of cases by ATCvet, pharmaceutical form and authorisation procedure

Third set includes a map representing the number of cases by authorisation country, a tree map for the number of cases by medicinal product authorisation number and finally a bar chart with the Top 15 number of cases by medicinal product:



Image 131: number of cases by authorisation country, number of cases by product and authorisation number and Top 15 number of cases by medicinal product

Lastly, two extra pie charts show the number of cases by MAH and by Species for the product or products selected in the filters page:



Image 132: Number of cases by MAH and by Species

11.2.1. See details

See 4.2.1. See Details.

11.3. List of products and substances without AERs associated

The second tab in 'list of products' dashboards will retrieve those products and substances that do not have any report associated. It means they were not reported in any AER.

ters	List of products	List of products and substances without AERs associated			
	Medicinal produ	ict code Medicinal product	Medicinal product shortname	Active substance code	Active substance
	6000000084	Aftovaxpur DOE (60) O1 BFS + SAT2 Saudi Arabia	AFTOVAXPUR DOE	10000075987	HUMAN MEASLES IMMUNOGLOBULIN
	60000000085	Aftovaxpur DOE (61) O Taiwan 3/97 + SAT2 Saudi Arabia	AFTOVAXPUR DOE	10000075988	HUMAN PLASMA FOR FRACTIONATION
	6000000086	Aftovaxpur DOE (62) A22 Iraq + SAT2 Saudi Arabia	AFTOVAXPUR DOE	10000075989	HYDROCHLORIC ACID, CONCENTRATED
	60000000094	Aftovaxpur DOE (41) O1 Manisa + A Turkey 14/98 + Asia1 Shamir	AFTOVAXPUR DOE	10000075990	DILUTED HYDROCHLORIC ACID
	60000000097	Aftovaxpur DOE (32) O1 Manisa + O1 BFS + Asia1 Shamir	AFTOVAXPUR DOE	10000075991	HYDROGEN PEROXIDE SOLUTION (3 PER CENT)
	60000000098	Aftovaxpur DOE (33) O1 Manisa + O Taiwan 3/97 + A22 Iraq	AFTOVAXPUR DOE	10000075992	HYDROGEN PEROXIDE SOLUTION (30 PER CENT)
	60000000122	Aftovaxpur DOE (34) O1 Manisa + O Taiwan 3/97 + A24 Cruzeiro	AFTOVAXPUR DOE	10000076067	Mevalonic acid
	60000000142	Aftovaxpur DOE (63) A24 Cruzeiro + SAT2 Saudi Arabia	AFTOVAXPUR DOE	10000076068	Midazolam maleate
	60000000232	Aftovaxpur DOE (54) O Taiwan 3/97 + A24 Cruzeiro + Asia1 Shamir	AFTOVAXPUR DOE	10000076070	MILLET
	60000000312	Aftovaxpur DOE (74) O1 BFS + A24 Cruzeiro + SAT2 Saudi Arabia	AFTOVAXPUR DOE	10000076071	Minaprine dihydrochloride
	60000000313	Aftovaxpur DOE (75) O1 BFS + A Turkey 14/98 + SAT2 Saudi Arabia	AFTOVAXPUR DOE	10000076074	COD-LIVER OIL (TYPE B)
	60000000314	Aftovaxpur DOE (77) O Taiwan 3/97 + A22 Iraq + SAT2 Saudi Arabia	AFTOVAXPUR DOE	10000076075	COLA
	60000000315	Aftovaxpur DOE (78) O Taiwan 3/97+ A24 Cruzeiro + SAT2 Saudi Arabia	AFTOVAXPUR DOE	10000076077	Copovidone
	60000000321	Aftovaxpur DOE (17) O1 BFS + A Turkey 14/98	AFTOVAXPUR DOE	10000076081	COUCH GRASS RHIZOME
	60000000322	Aftovaxpur DOE (20) O Taiwan 3/97 + A24 Cruzeiro	AFTOVAXPUR DOE	10000076085	Decyl oleate
	60000000327	Aftovaxpur DOE (23) A22 Iraq + A24 Cruzeiro	AFTOVAXPUR DOE	10000076087	DEVIL'S CLAW ROOT
	60000000328	Aftovaxpur DOE (31) O1 Manisa + O1 BFS + A Turkey 14/98	AFTOVAXPUR DOE	10000076088	DEXTRAN 1 FOR INJECTION
	60000000332	Aftovaxpur DOE (49) O1 BFS + A24 Cruzeiro + Asia1 Shamir	AFTOVAXPUR DOE	10000076089	DEXTRAN 40 FOR INJECTION
	60000000459	Aftovaxpur DOE (58) SAT2 Saudi Arabia	AFTOVAXPUR DOE	10000076090	DEXTRAN 60 FOR INJECTION
	60000000472	Suvaxyn CSF Marker () - Lyophilisate and solvent for suspension for injection	SUVAXYN CSF MARKER	10000076091	DEXTRAN 70 FOR INJECTION
	60000000480	Aftovaxpur DOE (59) O1 Manisa + SAT2 Saudi Arabia	AFTOVAXPUR DOE	10000076093	Dibutyl phthalate
	60000000481	Aftovaxpur DOE (24) A22 Iraq + Asia1 Shamir	AFTOVAXPUR DOE	10000076095	Diethyl phthalate
	60000000482	Aftovaxpur DOE (25) A24 Cruzeiro + A Turkey 14/98	AFTOVAXPUR DOE	10000076098	DIGITALIS LEAF
	60000000483	Aftovaxpur DOE (26) A24 Cruzeiro + Asia1 Shamir	AFTOVAXPUR DOE	10000076099	DIHYDRALAZINE SULPHATE, HYDRATED
	60000000484	Aftovaxpur DOE (27) A Turkey 14/98 + Asia1 Shamir	AFTOVAXPUR DOE	10000076101	DIPHTHERIA, TETANUS AND PERTUSSIS VACCINE (ADSORBED)
		🗛 🖓 🔒 🗿 Rows 1 - 25			A A B Rows 1 - 25

Image 133: List of products and substances without AERs associated

12. Pharmacovigilance inspections dashboard

The inspections dashboard is used to view the outcomes of the Pharmacovigilance (PhV) inspections that have been registered in IRIS. It displays, depending on the user's input, either a PSMF list that contains at least one CAP (centrally authorised product) with the corresponding dates related to the latest inspection of the PSMF, or a list of PSMFs that do not contain CAPs.

This dashboard can only be accessed by NCAs.



Image 134: Inspections dashboard tabs

12.1. Filters

Filters in this dashboard are distributed in the following manner:

1. PSMF

The user can select specific details regarding PSMF like reference, location and product MAH.

P	SMF reference	Select Value	-
PSMF loca	tion (country)	Select Value	-
PSME MAH (product MAH)	Select Value	-

Image 135: PSMF Filter

- PSMF reference
- PSMF location (country)
- PSMF MAH (product MAH)
- 2. Inspections

2. Inspections	
Supervisor authority Reporting inspectorate	Select Value 💌

Image 136: Inspections Filter

- Supervisor authority
- Reporting inspectorate

12.2. PSMF last inspection

It displays a table containing a list of PSMF's covering at least one CAP. There is a filter available at the top of the dashboard for this.

It also displays PSMF location and reference and the MAHs related to each of those PSMFs. The latest pharmacovigilance inspection starts, and end date is also available in the table with QPPV for each PSMF.

Contain CAP 🗍 No 🗍 Yes								
PSNF Company	Country	Address	Last inspection	Start Date	End date	Recomendations QPPV Country	QPPV Address	Q ^{opy} Name
Balvach - Drink - Drinket								

Image 137: PSMF last inspection table contents

Inside the 'PSMF' column the user is able to click and generate two different line listings, one per products listing and the other per inspection listing for the selected PSMF.

PSMF	Company	Country
0 0 0	PSMF Products listing PSMF Inspections list) ing

Image 138: PSMF line listing options (PSMF column)

Inside the 'Last inspection' column the user is able to click and generate a line listing showing the products for that inspection for that PSMF.

Last inspectio	n Start Date End dat
	Inspection products details

Image 139: PSMF line listing option (last inspection column)

12.2.1. PSMF products listing

It re-directs to a line listing table showing all the products covered by the current PSMF. The table consists of product short name, product name, product code, procedure type name, scientific product and MAH for the selected PSMF product.

12.2.2. PSMF inspections listing

It re-directs to a line listing table showing the inspections covered by the current PSMF. Table consists of inspection, start date, end date, country, company, address, supervisor authority, reporting inspectorate, recommendations, finding and grading.

12.2.3. Inspection products details

It re-directs to a line listing table showing products in the current PSMF at the time and location of this inspection. The table consists of inspection, start date, end date, product short name, product name, product code, procedure type name, MAH, QPPV country, QPPV address, QPPV name.

13. Sales Dashboard

This dashboard presents the sales data and incidence for all products for a selected period. This dashboard can **only** be accessed by NCAs.



Image 140: Sales dashboard tabs

13.1. Filters

Filters in this dashboard are distributed in the following manner:

1. Product information (required)

User can select each medicinal product for which sales data is informed. It is not necessary to complete this information if you have filled out the MAH.

- Product short name
- Product group name
- Medicinal product

1. Product information (Req	uired)						
Product short name	Select Value	~					
Product group name	Select Value	~					
Medicinal product	Select Value	~					
It is not necessary to c	It is not necessary to complete this information if you have filled the MAH.						

Image 141: Product information (required) filter

2. Sales data period (required)

Multiselect option must retrieve the complete years from sales data:

- Users can select one-year, multiple years or 'select all' option.
- When the filter is selected, the data that retrieved should be regarding the sales in that period (not related to AERs) --> Sales of 'X' product during the informed/selected period (year(s)).

2. Sales data period (Req	juired)	
Sales data period	NULL	

Image 142: Sales data period (required) filter

3. Product MAH filter

By using 'Product MAH filter', it is possible to filter by one specific MAH, so the output of the query will only be data related to the informed MAH (its products). Please note that you will at present only get results for MAHs with products for which there are adverse event reports.

3. Product MAH filter
Medicinal product MAHSelect Value 💌
Please note that you will at present only get results for MAHs with products for which there are adverse event reports.

Image 143: Product MAH filter

4. VedDRA terms

In this prompt the user can select one or multiple VedDRA terms at different levels.

- VedDRA Term SOC
- VedDRA Term HLT
- VedDRA Term PT
- VedDRA Term LLT



Image 144: VedDRA terms filter

5. Species

This filter retrieves all possible values if it was not informed in the filters page (if this information was given in the filters page, this field must only give the informed value in the filters page). The value(s) is retrieved based on the 'Species' related to each product in UPD (NOT affected species regarding AERs).

5. Specie		
:	peciesSelect Value 🔽	

Image 145 : Species filter

6. Region/country

It must retrieve information regarding the sales data and not related to the AERs. The possible values are the following ones:

- EEA
- Non-EEA
- Unknown

Depending on the region selected it will filter out the specific country the user can select for a more specific analysis.

6. Region/coun	try	
Region	Select Value 💌	CountrySelect Value

Image 146 : Region/country filter

13.2. Sales data and incidence overview

This dashboard displays the sales data information at medicinal product level, calculating:

- Volume of sales
- ENTA (estimated number of animals treated)
- Incidence calculation

The user is also able to re-select filters here again that apply to all the reports in this tab like sales data period, species, region/country.

The left side of the dashboard displays graphs related to sales and the right side of the dashboard displays graphs related to incidence.

Sales data and incidence overview

Composed of two maps and their respective tables below:

- Left map shows the volume of sales per country (hover over to see details). Below it displays a table with the same information, moreover, including the ENTA.
- ENTA (estimated number of animals treated) = No of units sold x %species x Dose Factor
- The right map shows the %incidence per country (hover over to see details). Below it displays a table with the %incidence for each of the PT VedDRA terms names (available filter).
- % incidence = (total number of animals displaying during a defined period/estimate of the number of animals treated during the same period) x 100

Solar data particit 2004 🛛 💌	Speder Neierlaube 💌	pargion which when 👿 Country Weind Wiles 👿						
Sala bia cella si la dia ce anti-								
Μησίαν ηχού κατά το το ματικό γ		Mapolawa gNaki Azar, po kazali y						
Safety Builde		Zadirah Kale Kalendi Karadi						

Image 147: Sales data and incidence overview (skeleton)

Both tables also include a dimension called Product Hierarchy Level to choose by which the user would like to display the data inside the left column of the table.



Image 148 : Product hierarchy level tables displaying volume of sales & %incidence

13.2.1. Line listing sales data

Available in the left-hand table when the user clicks on the specific medicinal product from the product hierarchy level chosen inside the column, they are able to generate in a separate report a line listing regarding sales.



Image 149: Line listing for sales data

- When the user selects 'Medicinal product short name', it should get all the medicinal products sold under each product short name in the selected period.
- When the user selects 'Product group name', it should get all the medicinal products under the same Product grouping ID that have been sold in the informed period.

Sales Data and Incidence per year

Composed of a bar chart displaying volume of sales (bar) and % incidence (line) per year and selected Product Hierarchy Level dimension. (hover over bar to see details).

13.2.2. Incidence calculation see details

At the bottom of the dashboard there is a text available to click: 'Incidence calculation see details':



It is composed of two tables with three columns:

- Top Table: Medicinal product chosen from Product Hierarchy Level Dimension, VedDRA SOC, %incidence
- Bottom Table: Medicinal product chosen from Product Hierarchy Level Dimension, VedDRA term chosen from VedDRA Hierarchy Level, %incidence

Based on the Product Hierarchy Level the results in the tables must show the corresponding VedDRAs that have been submitted. Global filters for both tables include Species, Year and Occurrence Country.

14. How to group data for different products

14.1. Introduction to product grouping

For contextual purposes, this grouping is related to 3 main scenarios:

- Grouping products with different names but referring to the same Medicinal Product. •
- Grouping data based on the composition by selecting Scientific Product or Active Substance
- Ad-hoc aggregations for random analysis purposes •

The guide will focus mainly on the first scenario and 2 specific medicinal products, analysing in detail how to group them as well as how this grouping impacts in the metrics recalculation. As mentioned, the analysis will consider:

- Active substance ENROFLOXACIN
- Products **PRODUCTX** and **PRODUCTX OTIC**
- MAH BAYER B.V. HEALTHCARE ANIMAL HEALTH and BAYER S.P.A •

14.2. Demo

Static RDR evaluation

havioural disorders

- Active substance ENROFLOXACIN
- Products **PRODUCTX** and **PRODUCTX OTIC**
- MAH BAYER B.V. HEALTHCARE ANIMAL HEALTH and BAYER S.P.A. •

Kolonel product shertmane						
	VelOFA SOCIMIE	Number reacted	A - Reports with product and reaction B - Reports with	hpreduct vetheral reachers C - Reports witho	ut product but with reaction D - Reports within	at product and without reaction IROR.(-) ROR. (ROR.(+)
	Application site disorders	5	5	185	6,815	164,511
	Schevicurei disordiers	- 23	23	165	11,479	15 (52 157 157 95
	Bloed and lyreshatic system decoders		30	164	2,953	167,477 11.43
	Cerdio-vascular system deproters	34	34	157	11,451	158,975 3.81 3.82
	Digestive haid disorders	. 95	55	52	49,295	121.361 2.65 3.25
	Ear and Movinth departent	20	20	171	\$,061	165,265 118 1.75 4.76
	Brid with Kisystem districts	10		181	2.828	165,355 163 5.31
	Ese Eduneit	24	2	163	6,118	100,000 100 100 4.20
	repeto e la y obortera	20		415	2,494	10,000 000 000 000
	BARDE SYSEE DOORDS	15	15	100	10,007	196.639 LAS 8.97 LAP
	are entry states	101		87	22,820	240,400 101 10 10 10 10 10 10 10 10 10 10 10
	Platebol on and a billion devolution			120	500	100 041 000 000 000
	Photo dedicted algorithms	20	38	144	6 882	147.045
	NIA			199	301	170.775 814 814 814
	Repartment discolory	87	*1	191	10.245	176.161 100 100 277
	Reeal and a many disarders	31	15	160	6462	161.964 648 4.82 5.25
	Reproductive system disprogra-	8		185	1,200	100,100 5.04 5.04
	Pesevatory part disorders	51	52	139	13.131	157,295 148 5.30
	Skin and appendages depident	20	30	171	35,591	153,635 9.83 1.69 1.26
	Statemic disorders	352	162	29	115,211	57 315 2.85 -1.97
	Unclass Bable event	1	1	190	797	266,639 N/A N/A N/A
	Uncoded signs	3	3	100	1,505	168,531 1.42 1.65
100 Mar 100	Application site disorders	- 2	2	29	6.810	164.503 Rev R/A
	Behaviourel depiritiers	4	4	27	13,493	15 063 1.72
	Digestive tract disorders	2.2	2	29	49,362	UID 221 NO. NO. NA
	Ear and labyrinth disorders	20	28	2	\$,253	LC5,433 289 64 929.39
	Eye disorders	3		28	8,138	164,448 2.87 4.16
	Investigations	- 5	5	26	36139	146,447 3.83 1.35 2.90
	Neurological disorders		1	27	34,320	236,285 0.40 0.53 0.86
	Reral and among disarders		2	29	6.491	164.085 N/A N/A N/A
	Sien and appencieges disorders	4	4	27	35,607	153,979 0.94 1.37 2.30
	Systemic disorders	6		251	113.267	57,319 0.08 0.12 0.18

13,474

156,952

We filter by VedDRA SOC up in the dashboard, so we only see the 2 products under analysis, PRODUCTX and PRODUCTX OTIC and their respective metrics:

			(Verter SCC in	ure Behave of South + 100	PART case Story Roles-	S WADRI	PT care [-felot value]#] veites ut	nana [-iislay titlay]a
oduct Hierorchy Level 🕅	ectionel product shorts	Inc Y VelDRA	National Level Velleta S	OC ADDE 💙					
odact Hierarcha Level (* Speces (<u>Dog </u>	stionel product sharts	vefbia	Dataat Level VedDita 5	00 aane ♥					
odat Herardia Level (* Speces (Deg v) odchal protet stortwere	elionel product sharts Vectoria SOC norm	ne Veloka	Autout Level Veltitia S	oC some ♥] si reaction.]≣ - Repr	eta with product witheut reaction (C	- Reports without anotaci but wit	h reaction D - I	Sports without product and rutificest reaction 1908	() PCR ROR (+)
odact Hierarchie Level (H Species (Dog V) odicinal product shortware	Vestina ordut shats Vestina Soc sens	Rumber reached 4	-Reports with product en	of name ¥ : direction [2 - Repr 23]	2) mittaer traditio tradem dive at a	- Rapota willout product but wit	reaction D - I	Separts without product and reflect reaction 1926 155,450	() ROR ROR (+) 1.59 1.66

Image 152:Static ROR with VedDRA SOC filter applied

After removing the product (by clicking on the column header and then on "exclude column") the system deletes the Medicinal Product column and recalculates the RORs :

SDECIES LAIDACA	~			
Addicinal product sl	Sort Column	>	ne	Number re
Draxotin			isorders	
	Exclude column		ystem disorders	
	Include column	>	rs	
	Maura Calvinna			

Image 153: Menu option where user can exclude column from table



Image 154: Recalculation from ROR after removing column split with of medicinal products

$$\mathsf{ROR} = \frac{27/195}{13.470/156.925} = 1.61$$

15. Dashboard walkthrough

The purpose of this dashboard walkthrough is to make an itinerary through the different dashboards implemented, focusing the analysis on its diverse functionalities depending on the potential business scenarios.

The itinerary will cover the user's decision-making process, depending on a series of factors which will determine using one dashboard or group of dashboards to conduct a specific analysis.



Image 155: Dashboard walkthrough

As a general rule, here's a schema of which dashboard is the most appropriate depending on the purpose of the query and what kind of information the user is trying to obtain:

- Adverse Event Overview: To get a simple overview of the data for a product, substance, groupof products
- **Signal Detection:** To view data for product, active substance, group of products in order to check for potential signals
- **Signal Evaluation:** To evaluate signals (age, time to onset, off label use, geographical distribution, pharmaceutical form, other products involved, other VedDRA terms)
- Data Stratification: To exclude outliers or simply narrow a query for comparison purposes
- Adverse Event Between 2 Periods of Time: To compare data for 2 time periods
- Line Listing: To list the cases for a product, substance, group of products, MAH, country
- Signalling for Reactions: To monitor data for MAH/NCA products or substances (weekly,monthly)
- **List of Products:** To monitor number of cases (by active substance, product, pharmaceutical form, ATCVET, authorisation country, number, MAH, species)

In terms of searching for concrete metrics or products, some useful tips for the user would be:

- **Number of Cases:** When the question is about the number of cases for a product, the user should use the Adverse Event Overview dashboard.
- **Statistical measure of signals:** In order to know about the type of reaction with relative frequency at a specific level, the user should go either through the Adverse Event or the Signal Detection Dashboards.

- **Products involved:** In regards of the products involved in a specific group of cases, the user should either go to the Data Stratification Dashboard or jump to it from the Adverse Event Overview query by using the link at the bottom.
- **Number of fatalities**: To see the number of animals treated with a product and died or euthanized as a consequence of this, the user should go to the Signal Evaluation and selecting a concrete period and VedDRA terms (death, death by euthanasia).
- **Period analysis:** If the user wants to see the number of cases within a period or from a specific date onwards, Adverse Event Overview is the way to go.

In this sense, we will divide those potential business scenarios in 3 different paths, depending on the profile of the user and/or the purpose of the analysis, just as follows:

- 1. Standard data exploring query for both NCA and MAH users.
- 2. MAH users monitoring their own products or ingredients on a weekly/monthly basis.
- 3. NCA users conducting an active substance class -based analysis.

15.1. Standard path

In the case of what we have named "standard path", we will go through a set of practical questions for a concrete product and reaction, in this case a signal has been found for **Product A** for the VedDRA term <u>recumbency</u>, so the following concerns emerge in a standard analysis process:

15.1.1. How many cases for Product A have occurred?

- The user goes to dashboard Adverse Event Overview and selects Product A in the firstprompt in the filter Product Shortname
- Enter the Message Received Date range as required. i.e. 1 year
- Select VedDRA Hierarchy, VedDRA PT name = Recumbency and tick the box for "Animal" and then run the query

15.1.2. Which signs have been reported on the cases of Product A at PT level? Which PT VedDRA terms have the highest number of reports?

- In the same dashboard (Adverse Event Overview) the user can see a table with all VedDRA terms reported in the cases for the product at SOC level
- Go to "See details" and a table will appear with the cases at PT level, or...
- Click the link to Signal Detection and go to the tab "Signal detection with 2 RORs"

15.1.3. Where have the majority of the cases occurred? How many animals have been affected?

- In the Adverse Event Overview, the user clicks on Animal/Human adverse events overview which is a link to the Signal Detection dashboard
- It will automatically navigate to the Overview of human/animal AERs per product/active substance/ATCvet code tab
15.1.4. Are other products involved?

- Go to the "Signal evaluation" dashboard and select Product A in the first prompt in the filter "Product short name".
- Enter the "Message received date range" as required i.e. last 5 years
- Select "VedDRA Hierarchy, VedDRA PT name = Recumbency". Tick the box for "animal" in the 4th prompt and then run the query. Go to the "Product association" tab

15.1.5. How many animals treated with Product A, have died? How many of those have been euthanised?

- "Adverse event overview" query gives you the number of animals died (Select Product A, click the animal box and make sure to select the dates that include the whole period when Product A has been on the market)
- To see the number of animals euthanised, select the VedDRA term LLT "Death by euthanasia".

15.1.6. How many cases have been reported between 01/03/2016 and 31/05/2016 and how many cases in total?

- "Adverse event overview"" select Product A, and select the dates.
- In the column "Number of cases (Period specified)", you have the n. of cases for specified period. To see the total n. of cases, either remove the date filters, or go to "see details". In the column "N. of cases (Total ALL)" you have the n. of total cases in the database per VedDRA term
- In the column "N. of cases (Case count (filter not applied)" you have the n. of total cases for the product.

15.1.7. Which other products are associated with recumbency? Which product has the highest number of cases of recumbency after Product A?

- Go to the "Data stratification" dashboard and select "VedDRA terms, VedDRA PT name = Recumbency"
- Then click on "and", then select "VedDRA term PT = Death"
- Tick the box for "Animal" then run the query by clicking on "Adverse events by VedDRA terms. The first graph will give you the answer

15.1.8. Which other signs have been reported together with recumbency? Which pair has the highest count?

- Go to the dashboard "Signal Evalution" and select Product A in the first prompt in the filter "Product short name"
- Enter the "Message received date range" as required e.g. last 5 years
- Tick the box for "animal" in the 3rd prompt.
- Select "VedDRA Hierarchy, VedDRA PT name = Recumbency" and go to "Associated VedDRA"

15.2. MAHs path

In the case of MAH users, we will follow 2 different potential scenarios.

15.2.1. Continuous monitoring scenario (with two alternatives):

1. List of Products:

- Use "Product MAH" filter to get an overview of data for all products owned by MAH, with or without "Product authorisation procedure" and/or "Product authorisation country"
- Select specific product(s), active substance(s) or ATCVet codes to focus the analysis on a specific area

2. Signalling for reactions linked to a product or ingredient:

- Run signalling for reactions linked to a product or ingredient to find potential new signals.
- Frequency: Weekly, monthly...

15.2.2. Product-based analysis scenario (with four alternatives):

- 1. Adverse Event Overview: To obtain baseline data: Number of AERs per product and species, Number of animals affected, Number of fatalities
- Signal Detection: To view the type of Adverse Events reported for a selected product or group of products (at SOC and PT) and to compare the frequency to the number of reports involving other products and other clinical signs = ROR / ROR(-)
- 3. Signal Evaluation: To analyse the profile of affected animals (i.e. breed, age) for adverse reactions of interest (potential signs) and identify potential risk factors, effects of co-medication, geographical distribution or pharmaceutical form
- 4. Data Stratification: To compare a product to products of the same class, or to identify and exclude certain products from the comparison (products with a disproportionate number of reports for a specific AE)

15.3. NCAs path

To conduct an active substance class-based analysis for a class of products (e.g. antiparasitics), some guidelines should be taken into account, such as:



In the case of NCA users, this active substance class-based analysis is therefore based on the following generic 2 steps methodology and the dashboards associated to do so:

Define baseline: Identify the products and their active substances, target species, pharma forms, any combination products:

- Collect sales data
- Run queries to get overview of the number of reports in the database (per active substance / pharma form /species)

This defining baseline procedure would be achieved using the Adverse Event Overview dashboard.

AEs profile in target species (including human reactions): What is the clinical profile of adverse reactions in each target species: is there a "class effect", a disproportion of reporting of a given sign for a particular product/active substance/pharma form, or for the entire group:

- Profile of affected animals (e.g. breed, age) for all adverse reactions
- Effect of co-medication
- Incidence calculation
- ROR with/without stratification (antiparasitics)

This profiling step would be achieved on the other hand by using Signal Detection, Signal Evaluationand Data Stratification dashboards.

Summing up:

- **Define baseline:** Number of AEs for all the products per species, Number of AEs per product and species, Number of affected animals/Number of fatalities.
- **Clinical profile and comparison with the current SPCs:** To capture the clinical profile of adverse reactions focusing on medically important events, obtain the number of reports per VedDRA term at SOC and PT level. To identify similarities and differences in this profile based on the species, pharmaceutical form, therapeutic class:
 - Global (all substances/products)
 - Tablets versus spot-on
 - Per active substance
 - Per product
- Relate the number of adverse event reports for a particular product or group of products:
 - To the sales volumes of this product/group of products = INCIDENCE
 - To the number of reports involving other products and other clinical signs= ROR.
- **ROR analysis:** For selected PTs, in each species, calculate a ROR for each product in comparison to:
 - All the products included in the subgroup analysis.
 - o Only the products with the same route of administration withing the subgroup analysis.
 - Exclude potential overrepresented products based on the VedDRA term of interest.

16. Annex

16.1. KPIs explanation

- **Number of cases**: Number of cases with the same Case number within the adverse event report.
- **Number of animals affected:** Animals affected within the adverse event report which will also include indirectly exposed animals, e.g. treated during pregnancy or lactation, co mingled, infectious spread, etc.
- **The total number of animals affected includes**: Recovered/Normal, Recovered with Sequela, Died, Euthanized, Unknown.
- **Number of animals reacted:** Animals experimenting reactions to VMPs within the adverse event report.
- **Number of animals died:** Animals died as a consequence of an adverse reaction to VMPs within the adverse event report.
- The total number of animals died includes: Died, Euthanized.

16.2. ROR

16.2.1. ROR calculation

The Reporting Odds Ratio (ROR) calculates the odds of a certain event occurring with your medicinal product, compared to the odds of the same event occurring with all other medicinal products in the database.

A signal is considered when the lower limit of the 95% confidence interval of the ROR is greater than one. The 95% confidence interval gives an indication of the precision of the estimate of the ROR.

For instance, if the ROR is 3, the odds of reports of this event with the medicinal product are x3 times higher than the odds of reports of this event among all other reports in the database.



Image 156: ROR Calculation formula

16.2.2. ROR calculation for data stratification

ROR calculation for data stratification follows the same logic as the regular ROR calculation does. Same 4 variables apply, this is:

- Number of cases with the VedDRA term and without the VedDRA term
- Number of cases with the Product and without the Product



Image 157: ROR calculation for data stratification

It is important to state that changes in the scope (Products or Species involved in the calculation) will impact in the ROR metrics since these modifications have a direct impact in the variables of the formula explained in the ROR Calculation (See 14.2.1 ROR Calculation) and potentially changing the outcome.