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Information Management Division

EVVet3 Production – Release notes

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Table of Contents

1. Version 20JAN2023.....	3
1.1. Overview.....	3
1.2. New improvements from last version:	3
1.3. Existing issues version 20JAN2023.....	3
1.4. Fixed issues from last version.....	4
2. Version 08AUG2022.....	4
2.1. Overview.....	4
2.2. New improvements from last version:	4
2.3. Existing issues version 08AUG2022.....	5
2.4. Fixed issues from last version.....	5
3. Version 21JUL2022	5
3.1. Overview.....	5
3.2. New improvements from last version:	5
3.3. Existing issues version 21JUL2022	6
3.4. Fixed issues from last version.....	6
4. Version 04JUL2022	6
4.1. Overview.....	6
4.2. New improvements from last version.....	7
4.3. Existing issues version 04JUL2022	7
4.4. Fixed issues from last version.....	8
5. Version 07JUN2022.....	8
5.1. Overview.....	8
5.2. New improvements from last version.....	8
5.3. Existing issues version 07JUN2022.....	8
5.4. Fixed issues from last version.....	9
6. Version 11MAY2022	9
6.1. Overview.....	9
6.2. New improvements from last version.....	10
6.3. Existing issues version 11MAY2022	10
6.4. Fixed issues from last version.....	11
7. Version 20APR2022.....	12
7.1. Overview.....	12
7.2. Existing issues in version 20APR2022	12
7.3. Fixed issues from last version.....	13
8. Version 28JAN2022	13
8.1. Overview of EVVet3 functionality	13
8.2. Functionalities.....	13
8.3. Existing issues in version 28JAN2022	14

1. Version 20JAN2023

1.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database, 20JAN2023.

This version introduces amendments for some incorrect breed mappings and Veddra LLT codes, new business rule for Nullifications and Follow-ups and DWH improvements.

1.2. New improvements from last version:

Issue ID	Description	Component
EVVET3-13201	Process of rerouting cases to NCAs has been improved adding a retry process, with up to three additional attempts, when ACK is not received.	Messaging
EVVET3-13515 EVVET3-12906	New business rule to restrict nullifications and follow-ups of VICH and DEG cases only to the Original sender of the first valid case	Messaging
EVVET3-12953	DWH-OBIEE Access policy implementation	DWH
EVVET3-13738	AER data for NON-CAPS products now available in Public reports website	DWH
EVVET3-12951	Performance improvement: Split results table from <i>Signal detection</i> dashboard into 3 separate tables (Signal detection with 2 RORs, up to Date 1 and up to Date 2)	DWH
EVVET3-13755	New tab to retrieve all products and substances that do not have any report associated from <i>List of products</i> dashboard.	DWH
EVVET3-13631	'Switch to table' functionality has been added to all graphs from <i>Signal evaluation</i> dashboard	DWH
EVVET3-13471	Product hierarchy selector has been added to <i>Associated product</i> sub-report from <i>Adverse event overview</i> dashboard	DWH
EVVET3-12802	Product hierarchy selector has been added to <i>Product association</i> tab from <i>Signal evaluation</i> dashboard	DWH
EVVET3-13623	'Switch to table' functionality has been added to all graphs from <i>Adverse event overview</i> dashboard	DWH

1.3. Existing issues version 20JAN2023

Issue ID	Description	Component
EVVet3-9647 EVVet3-8613 EVVet3-8612	The system may be slower than expected when executing some specific actions (e.g., running search by some criteria or log in)	EVWeb
EVVet3-12353	In the organisation list tab, when searching by country, the routing ID is not displayed for any organisation in the results	EVWeb
EVVet3-11678	In the search AER results table, for some reports, the VICH Batch received date, Species and classification field values are not displayed	EVWeb

Issue ID	Description	Component
EVVet3-11272 EVVet3-11273 EVVet3-11274 EVVet3-11275 EVVet3-14164 EVVet3-13810 EVVet3-13809	The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard.	DWH
EVVet3-13916	Adverse event overview and Data stratification - Line listing display irrelevant records	DWH
EVVet3-13122	Adverse event overview report - Issue with data in the graphs displaying data for last 10 years.	DWH

1.4. Fixed issues from last version

Issue ID	Description	Component
EVVET3-12693 EVVET3-12905	Breed mapping DEG/VICH incorrectly applied by system for 6 breeds	Messaging
EVVET3-13015	DEG dosage form "271 - premix for medicated stuff" has been remapped to VICH "C42969 - PELLET"	Messaging
EVVET3-13129 EVVET3-12497	Impossible to submit follow-up reports when Unique AER ID contains special character "/"	EVWeb
EVVET3-13129	Fixed 4011 affected reports that were incorrectly classified as error although no validity errors were detected	Messaging
EVVET3-14021	Validity errors with LLT Veddra codes 529, 530, 2354, 1909, 3035	Messaging
EVVET3-13287	Age and Weight information are not displayed in Line Listing	DWH
EVVET3-13203	In 'data stratification' dashboard, when using 'And not' operator from VEDDRA filter, the system is incorrectly retrieving the number of reports for the excluded Veddra terms.	DWH
EVVET3-12891	When 'Date of OnSet' in EVWEB is informed as MM/YYYY or YYYY, DWH is not retrieving the correct date.	DWH

2. Version 08AUG2022

2.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database, v. 08AUG2022

This version introduces a new functionality to Export in CSV the results table of a search in "Search AE Reports" section and corrections for some incorrect breed mappings.

2.2. New improvements from last version:

Issue ID	Description	Component
EVVET3-12161	New functionality to export the results table in "Search AE Reports" sections to a CSV file.	EVWeb

2.3. Existing issues version 08AUG2022

Issue ID	Description	Component
EVVet3-9647 EVVet3-8613 EVVet3-8612	The system may be slower than expected when executing some specific actions (e.g., running search by some criteria or log in)	EVWeb
EVVet3-12353	In the organisation list tab, when searching by country, the routing ID is not displayed for any organisation in the results	EVWeb
EVVet3-11678	In the search AER results table, for some reports, the VICH Batch received date and Species field values are not displayed	EVWeb
EVVET3-12693 EVVET3-12905	Breed mapping DEG/VICH incorrectly applied by system for 6 breeds	Messaging
EVVET3-12625	Classification criteria filter does not return the correct results	EVWeb
EVVet3-11272 EVVet3-11273 EVVet3-11274 EVVet3-11275 EVVet3-11276 EVVet3-11681	The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard.	DWH
EVVET3-13287	Age and Weight information are not displayed in Line Listing	DWH
EVVET3-13203	In 'data stratification' dashboard, when using 'And not' operator from VEDDRA filter, the system is incorrectly retrieving the number of reports for the excluded Veddra terms.	DWH
EVVET3-12891	When 'Date of OnSet' in EVWEB is informed as MM/YYYY or YYYY, DWH is not retrieving the correct date.	DWH

2.4. Fixed issues from last version

Issue ID	Description	Component
EVVET3-12551	Breed mapping DEG/VICH incorrectly applied by system for 17 breeds	Messaging

3. Version 21JUL2022

3.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database, v.21JUL2022.

This version introduces changes in the business rules applicable for AER submissions through EVWEB Application and Gateway.

3.2. New improvements from last version:

Issue ID	Description	Component
EVVET3-12743	Amended rule 92 to allow initial/other submissions with same Unique AER Number when occur country is non-EEA.	Messaging

Issue ID	Description	Component
EVVET3-12742	Rule 256 has been changed from Error to Warning, to allow submission of AERs when AER ID in field B.6.1. Linked Unique AER Number is not in the database and/or not in the same batch.	Messaging
EVVET3-12521	Rule 104 has been changed from Error to Warning, allowing the submission of a AERs when the number of animals affected is higher than the number of animals treated.	Messaging

3.3. Existing issues version 21JUL2022

Issue ID	Description	Component
EVVet3-9647 EVVet3-8613 EVVet3-8612	The system may be slower than expected when executing some specific actions (e.g., running search by some criteria or log in)	EVWeb
EVVet3-12353	In the organisation list tab, when searching by country, the routing ID is not displayed for any organisation in the results	EVWeb
EVVet3-11678	In the search AER results table, for some reports, the VICH Batch received date and Species field values are not displayed	EVWeb
EVVet3-12551 EVVET3-12693 EVVET3-12905	Breed mapping DEG/VICH incorrectly applied by system for 19 breeds	Messaging
EVVET3-12625	Classification criteria filter does not return the correct results	EVWeb
EVVet3-11272 EVVet3-11273 EVVet3-11274 EVVet3-11275 EVVet3-11276 EVVet3-11681	The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard.	DWH

3.4. Fixed issues from last version

Issue ID	Description	Component

4. Version 04JUL2022

4.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database, v 04Jul2022.

This version introduces changes in EvWeb report forms, removing any Personal Data information from the HTML and XML exports and from the EVVet Database, in compliance with EMA GDPR policy. Additionally, minor defects have also been corrected.

4.2. New improvements from last version

Issue ID	Description	Component
EVVet3-12359 EVVet3-12322	In the EvWeb HTML and XML exports, personal data information have been removed, in compliance with GDPR: <ul style="list-style-type: none"> - A.2.2 Person Acting on Behalf of MAH - A.3.2 Other Reporter - A.3.1 Primary Reporter (only Last Name, Country, and Primary Reporter Category fields are visible) A Datafix has been applied to wipe out this information from EVVet Database.	EVWeb
EVVet3-10941	Checkbox as a new filter has been included in all dashboards to get the results based only on the Medical Important Events.	DWH
EVVet3-13016	The minimum of 10 reports for getting results in ' <i>Signalling for reaction linked to a product or ingredient</i> ' has been eliminated.	DWH

4.3. Existing issues version 04JUL2022

Issue ID	Description	Component
EVVet3-9647 EVVet3-8613 EVVet3-8612	The system may be slower than expected when executing some specific actions (e.g., running search by some criteria or log in)	EVWeb
EVVet3-12353	In the organisation list tab, when searching by country, the routing ID is not displayed for any organisation in the results	EVWeb
EVVet3-11678	In the search AER results table, for some reports, the VICH Batch received date and Species field values are not displayed	EVWeb
EVVet3-12551	Breed mapping DEG/VICH incorrectly applied by system for 19 breeds	Messaging
EVVet3-11272 EVVet3-11273 EVVet3-11274 EVVet3-11275 EVVet3-11276 EVVet3-11681	The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard.	DWH
EVVet3-13205	MAH filter is not working as expected as it is retrieving wrong information (DWH dashboards and Analysis functionality)	
EVVet3-13203	When using 'And not' in VedDRA filter in <i>Data stratification</i> dashboard, it is not excluding the VedDRA terms selected.	
EVVet3-13122	In 'Adverse Event Overview' dashboard, graph regarding Last 10 years is not showing the complete 10 years. It is counting from the exact day the query is done.	

4.4. Fixed issues from last version

Issue ID	Description	Component
EVVet3-12544	In the search AER screen, a classification value has been corrected to "Duplicated" (from "duplicate"), both in the results table and criteria values.	EVWeb

5. Version 07JUN2022

5.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database, v 07JUN2022.

This version introduces changes in EvWeb report forms, removing any Personal Data information from the user interface, in compliance with EMA GDPR policy. Additionally, minor defects have also been corrected.

5.2. New improvements from last version

Issue ID	Description	Component
EVVet3-12359	In the EvWeb reporting forms, personal data fields have been removed, in compliance with GDPR: - A.2.2 Person Acting on Behalf of MAH - A.3.2 Other Reporter - A.3.1 Primary Reporter (only Last Name, Country, and Primary Reporter Category fields are visible)	EVWeb
EVVet3-11631	Both the catalog and the subject area have been renamed as 'EVVET3 DWH'	DWH
EVVet3-9876 EVVet3-9873	MAH filter has been added in the following dashboards: - Data stratification - Adverse event comparison between 2 periods	DWH
EVVet3-9868 EVVet3-9867	Seriousness has been removed both from all dashboards in the (1)Public reports and (2)DWH platform	DWH
EVVet3-7232	Breed filter values will depend on the selected specie in all dashboards	DWH

5.3. Existing issues version 07JUN2022

Issue ID	Description	Component
EVVet3-9647 EVVet3-8613 EVVet3-8612	The system may be slower than expected when executing some specific actions (e.g., running search by some criteria or log in)	EVWeb
EVVet3-12353	In the organisation list tab, when searching by country, the routing ID is not displayed for any organisation in the results	EVWeb
EVVet3-11678	In the search AER results table, for some reports, the VICH Batch received date and Species field values are not displayed	EVWeb

Issue ID	Description	Component
EVVet3-12551	Breed mapping DEG/VICH incorrectly applied by system for 19 breeds	Messaging
EVVet3-11272 EVVet3-11273 EVVet3-11274 EVVet3-11275 EVVet3-11276 EVVet3-11681	The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard.	DWH

5.4. Fixed issues from last version

Issue ID	Description	Component
EVVet3-11712	In the search AER results table, for some reports, Age field values are not displayed correctly (no decimals, duplicates values)	EVWeb
EVVet3-12101	When creating a report, it is no possible to link reports (section B.6) contained in the same batch.	EVWeb
EVVet3-12205	In the search AER results table, sorting fails for large dataset results	EVWeb
EVVet3-12163	When accessing any report, for some fields (i.e., Country, species, AER Term name, ATC, Receiver) a comma is displayed before the actual value in the UI. The defect doesn't impact the download (HTML/XML)	EVWeb
EVVET3-12536	Classification field names have been corrected in Search AE Reports results table, consistent now with criteria search values.	EVWeb
EVVet3-11987	In the line listing details, when the reported animal age was Unknown, the Datawarehouse reports displayed a '-1'	DWH
EVVet3-12558	Line listing from <i>Adverse Event overview</i> dashboard was open in the same window. Now it is open in a new window.	DWH
EVVet3-12437 EVVet3-12435 EVVet3-12434	The number of records displayed in the line listing does not match the number clicked in the following dashboards: - <i>Data stratification report – Line listing</i> - <i>Adverse event overview – Line listing</i> - <i>Signal evaluation – Product association tab – Line listing</i>	DWH
EVVet3-12358	In <i>Adverse event overview</i> dashboard, the <i>Number of fatal cases (Total all)</i> shows the same value as the <i>Number of fatal cases (period specified)</i>	DWH
EVVet3-11681	In the <i>Product stratification</i> tab from the <i>Data stratification</i> dashboard, graph number 2 is not loaded	DWH

6. Version 11MAY2022

6.1. Overview

This release is the next iterative version of the Union Pharmacovigilance Database, v 11MAY2022.

This version enhances the searches functionalities in the EvWeb application and improves the Signal Evaluation and Adverse Event Overview dashboards in the EVVet Datawarehouse.

6.2. New improvements from last version

Issue ID	Description	Component
EVVet3-11676 EVVet3-10977 EVVet3-11995 EVVet3-10758 EVVet3-11180 EVVet3-11983 EVVet3-12193 EVVet3-11994	In the Search AER section, criteria/filter and search results have been improved: <ul style="list-style-type: none"> - Sender, Product MAH, Occur country and Products/substance criteria filters are now multi select fields, allowing inclusion and exclusion - Report Classification has been added as criteria/filter and as field/column - Product and Substances criteria have been added as a fields/column in the results table - Sorting has been enabled for all the fields/columns where only one value exists - Product recoding date has been added as new criteria/filter and new field/column in the results table 	EVWeb
EVVet3-10935	The routing ID has been added next to the organisation name within the organisation's selector that is displayed after logging in.	EVWeb
EVVet3-12120 EVVet3-11883	Analysis by Scientific Product has been improved to retrieve only those reports with the right level of product information.	DWH
EVVet3-9402 EVVet3-9374	In the Signal Evaluation dashboard: <ul style="list-style-type: none"> - ATC vet name has been added next to the ATC vet code, for the Product information tab - Filtering by 'Unknown' products has been enabled, in the Product association tab 	DWH
EVVet3-9599 EVVet3-8888	In the Adverse Event Overview dashboard: <ul style="list-style-type: none"> - Lowest level of ATC vet is now displayed, in the See details section. - MAH filter has been added, in the filters section 	DWH
EVVet3-9601	In the Line Listing dashboard, the order of the tabs has been interchanged to make it more logical.	DWH

6.3. Existing issues version 11MAY2022

Issue ID	Description	Component
EVVet3-9647 EVVet3-8613 EVVet3-8612	The system may be slower than expected when executing some specific actions (e.g., running search by some criteria or log in)	EVWeb
EVVet3-12101	When creating a report, it is no possible to link reports (section B.6) contained in the same batch.	EVWeb
EVVet3-12353 EVVet3-12344	In the organisation list tab, when searching by country, the routing ID is not displayed for any organisation in the results	EVWeb

Issue ID	Description	Component
EVVet3-11712	In the search AER results table, for some reports, Age field values are not displayed correctly (no decimals, duplicates values)	EVWeb
EVVet3-11678	In the search AER results table, for some reports, the VICH Batch received date and Species field values are not displayed	EVWeb
EVVet3-12163	When accessing any report, for some fields (i.e., Country, species, AER Term name, ATC, Receiver) a comma is displayed before the actual value in the UI. The defect doesn't impact the download (HTML/XML)	EVWeb
EVVet3-12551	Breed mapping DEG/VICH incorrectly applied by system for 19 breeds	Messaging
EVVet3-12205	In the search AER results table, sorting fails for large dataset results	EVWeb
EVVet3-11987	In the line listing details, when the reported animal age was Unknown, the Datawarehouse reports displayed a '-1'	DWH
EVVet3-11272 EVVet3-11273 EVVet3-11274 EVVet3-11275 EVVet3-11276 EVVet3-11681	The system may be slower than expected when executing some specific actions (e.g., Drop, ordering columns on dashboard tables). Slow performance in data stratification dashboard.	DWH

6.4. Fixed issues from last version

Issue ID	Description	Component
EVVet3-11660 EVVet3-11703	The profile section does not show the correct Responsible Person Information	EVWeb
EVVet3-12189	In the Search AER section, searching by products and substances is case sensitive	EVWeb
EVVet3-12164 EVVet3-11900	When filling a new AER, for limited UPD products, the active substance and the procedure number are not retrieved after picking the UPD product	EVWeb
EVVet3-11615	There are some dosage forms that are missing in the collection Data Base. Example product: Ubrolexin intramammary suspension for lactating dairy cows Missing dosage form: Intramammary solution	EVWeb
EVVet3-11648	For some users it is not possible to download inbox/outbox messages	EVWeb
EVVet3-11142	When performing a search (from Search AE Reports) filtering by criteria ' <i>Correct report, with warnings, errors</i> ', does not retrieve the correct results	EVWeb
EVVet3-6581	When filling an AER, it is possible to deselect any radio button (e.g., Use according to label)	EVWeb
EVVet3-12323	In the <i>Adverse Event overview</i> , ROR is shown at all VedDRA levels in 'see details' view	DWH

Issue ID	Description	Component
EVVet3-12231	Some deprecated substances were considered active in the DWH dashboards.	DWH
EVVet3-12129	In the Adverse Event Overview dashboard, for edge scenarios, the line listing is not retrieving results	DWH
EVVet3-11896	Error message when logging out	DWH

7. Version 20APR2022

7.1. Overview

First release to production environment after Go Live regarding Pharmacovigilance VET3 system.

7.2. Existing issues in version 20APR2022

Issue ID	Description	Component
EVVet3-11142	When performing a search (from Search AE Reports) filtering by criteria ' <i>Correct report, with warnings, errors</i> ', does not retrieve the correct results	EVWeb
EVVet3-9647 EVVet3-8613 EVVet3-8612	The system may be slower than expected when executing some specific actions (<i>e.g.</i> , running search by some criteria or log in)	EVWeb
EVVet3-11660	Profile section does not show the correct Responsible Information	EVWeb
EVVet3-11615	There are some dosage forms that are missing in the collection Data Base. Example product: Ubrolexin intramammary suspension for lactating dairy cows Missing dosage form: Intramammary solution	EVWeb
EVVet3-11648	For some users it is not possible to download inbox/outbox messages	EVWeb
EVVet3-11900	Dropdown menu for UPD products (field B.2.1) should show the Authorization Identifier instead the procedure number	EVWeb
EVVet3-12101	Impossible to link reports (section B.6)	EVWeb
EVVet3-11445	Some duplicates values can be found in the list of <i>Primary Source Categorization</i> (section 6, optional report filter in Adverse event overview dashboard)	DWH
EVVet3-11272 EVVet3-11273 EVVet3-11274 EVVet3-11275 EVVet3-11276	The system may be slower than expected when executing some specific actions (<i>e.g.</i> , Drop, ordering columns on dashboard tables)	DWH

7.3. Fixed issues from last version

Issue ID	Description	Component
EVVet3-11469	Sometimes, when importing a report through an XML file, there are some fields that are not populated in the form. If user clicks on 'validate' or 'validate and Send', there are some missing validation messages that should appear regarding these missing fields (e.g., Country - A.1.4.1 field)	Messaging
EVVet3-11670	Warning message (rule 148) 'Registered Name or Brand Name: The field Registered Name or Brand Name - B.2.1 could not be matched against product and substance information database' appearing when selecting some products.	Messaging
EVVet3-11666	Domestic vs Foreign Report category field (B.8.2.6) is absent when downloading reports in XML format	EVWeb
EVVet3-8615	VeDDRA terms are not displayed in the UI when opening a report	EVWeb
EVVet3-11401	Download of HTML and XML reports in EVWEB is taking too long	EVWeb
EVVet3-11880	The line listings either takes a long time to appear or does not appear at all.	DWH
EVVet3-11688	Adverse Event Overview. Concerns the chart Number of cases and fatal cases (Last 10 years). The user can see a line listing report by clicking in any of the bars displayed within this chart (10 years span), but when clicked in a year not included in the filters previously set, line listing's column Number of Cases (Period Specified) is filled with zeros. The solution implemented is that, when the user clicks on those, the report shows no results.	DWH
EVVet3-11650	Analysis made by the user in the subject area didn't match with the table displayed within the Signal Evaluation dashboard - Product Association tab, link in the far left "Cases with no other products reported". Not all the species shown in the subject area were displayed in this report's dropdown.	DWH

8. Version 28JAN2022

8.1. Overview of EVVet3 functionality

This release to production environment will bring the new EudraVigilance Veterinary 3 (EVVet3) system live on the 28 of January 2022. The system, that is compliant with VICH guidelines, will be enhanced in future releases. From now the go-live of the system the EVVet2 system will be disabled, so the Adverse Event Reports (AERs) will need to be sent via EVVet3-EVWeb system.

8.2. Functionalities

Deployed features		
Access Management		Access policy
		Authentication and authorisation
Transactional system	EVWeb (AERs)	Create AERs

Deployed features		
		Submit AERs
		View AERs
		Import/Export AERs
		Follow-up / nullify AERs
		Search AER: <ul style="list-style-type: none"> • Search reports • Search Mailbox • Search VICH Batch
	<i>Message processing</i>	Process and load
		Business rules
		NCA Re-routing
		Compliance Dashboard
		MAH Dashboard
Data warehouse <i>(Analytics & Reporting AER)</i>	Signal detection	
	Public Dashboard	
	Signal evaluation	
	Data stratification	
	UPD Integration	
Data Processing	Products and Substance Recoding	

8.3. Existing issues in version 28JAN2022

Issue ID	Description	Component
EVVet3-11469	Sometimes, when importing a report through an XML file, there are some fields that are not populated in the form. If user clicks on 'validate' or 'validate and Send', there are some missing validation messages that should appear regarding these missing fields (e.g., Country - A.1.4.1 field)	EVWeb
EVVet3-11142	When performing a search (from Search AE Reports) filtering by criteria 'Correct report, with warnings, errors', the retrieved data is not the correct one	EVWeb
EVVet3-9648 EVVet3-9647 EVVet3-8615 EVVet3-8613 EVVet3-8612	In the EVWeb, the system may show some minor lower performance when executing some specific actions (e.g., running search by some criteria or log in)	DWH
EVVet3-11445	Some duplicates values can be found in the list of <i>Primary Source Categorization</i> (section 6, optional report filter in Adverse event overview dashboard)	DWH
EVVet3-11272 EVVet3-11273 EVVet3-11274 EVVet3-11275 EVVet3-11276 EVVet3-11277	In the DWH, the system may show some minor lower performance when executing some specific actions (e.g., Drop, ordering columns on dashboard tables)	DWH

