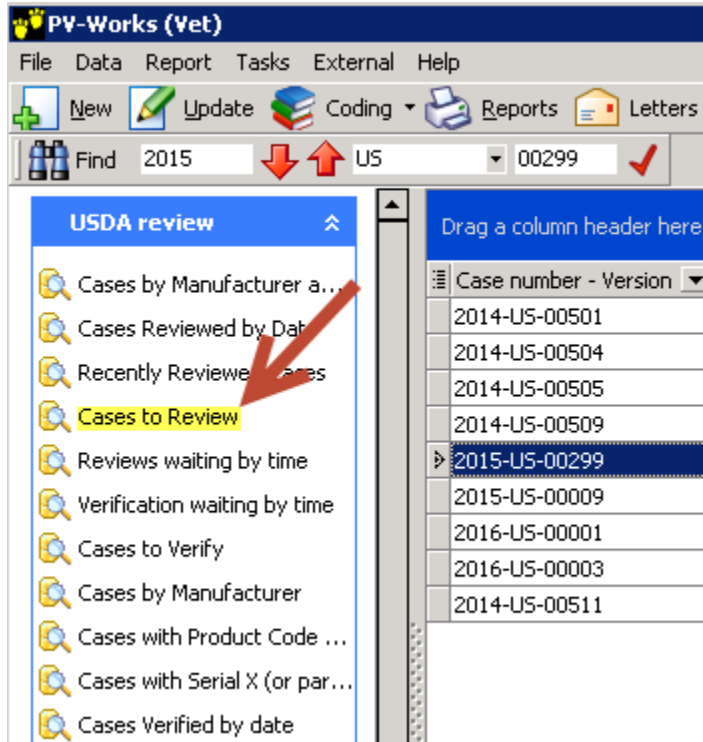


Reviewing, Coding and Assessing Adverse Event Reports in PV-Works

This document describes the procedures for reviewing, coding, and assessing Adverse Event Reports (AERs) in PV-Works database application.

Adverse Event Reports (also called cases) are entered and verified within PV-Works as per **ICWI0117**, *Entering and Verifying Adverse Event Reports in PvWorks*.

To find the list of cases ready for review, select the query “Cases to Review” on the left panel of the main screen.



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From the list of cases to review, select a case to highlight it and then open it by double clicking on it or selecting the red check mark next to the case number above as shown below:

The screenshot displays the PV-Works (Vet) application window. The main area shows a table of cases with columns for Case number - Version, Date first received, Case owner, Case type, Brand name (primary), and Species. The case 2016-US-00001 is highlighted in blue. A red checkmark is placed to the left of this case number. Two red arrows point to the checkmark and the case number, with text annotations: "Select here to open case" and "Double click here to open case".

Case number - Version	Date first received	Case owner	Case type	Brand name (primary)	Species
2015-US-00273	18-Nov-2015		Animal Complaint	Modified Live Virus	Dog
2015-US-00274	20-Nov-2015		Animal Complaint	Modified Live Virus	Dog
2015-US-00272	24-Nov-2015		Animal Complaint	Modified Live Virus	Dog
2015-US-00270	4-Dec-2015		Animal Complaint	Modified Live Virus	Dog
2015-US-00274	5-Dec-2015		Animal Complaint	Not given	Dog
2015-US-00281	8-Dec-2015		Animal Complaint	Killed virus	Cat
2015-US-00290	10-Dec-2015		Animal Complaint	Killed Virus	Dog
2015-US-00288	12-Dec-2015		Animal Complaint	Killed Virus	Dog
2015-US-00289	14-Dec-2015		Animal Complaint	Killed Virus	Cat
2015-US-00298	16-Dec-2015		Animal Complaint	Killed Virus	Cat
2015-US-00297	16-Dec-2015		Animal Complaint	Killed Virus	Cat
2015-US-00206	17-Dec-2015		Animal Complaint	Not given	Dog
2015-US-00291	17-Dec-2015		Animal Complaint	Not given	Dog
2015-US-00292	22-Dec-2015		Animal Complaint	Modified Live Virus	Dog
2015-US-00293	22-Dec-2015		Animal Complaint	Killed Virus	Dog
2015-US-00295	22-Dec-2015		Animal Complaint	Modified Live Virus	Cat
2015-US-00296	22-Dec-2015		Animal Complaint	Not given	Dog
2015-US-00294	22-Dec-2015		Animal Complaint	Live Canarypox Vector	Cat
2016-US-00003	29-Dec-2015		Product Problem Only	Not given	
2016-US-00001	5-Jan-2016		Animal Complaint	Killed Virus	Dog
2016-US-00001	5-Jan-2016		Animal Complaint	Modified Live Virus, AVIR...	Dog
2016-US-00004	5-Jan-2016		Animal Complaint	Killed Virus	Dog
2016-US-00006	7-Jan-2016		Animal Complaint	Live Canarypox Vector	Cat
2016-US-00007	12-Jan-2016		Animal Complaint	Killed Virus	Dog
2016-US-00008	12-Jan-2016		Animal Complaint	Killed Virus	Dog

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The case will open in the complaints screen (the default screen) as shown below:

The screenshot displays the PV-Works software interface for a case report. The window title is "2016-US-00001:Update". The case ID is "2016-US-00001" and the location is "USA". The case title is "Modified Live Virus, Avirulent Live Culture" and the description is "On October 19th, 2015, my 3 1/2 year old healthy Aussie/Colie mix received intr Anaphylaxis". The date is "5-Jan-2016".

The interface is divided into several sections:

- Case Details:** Case / Call type: Animal Complaint; Source: Owner / Producer / Emj; Country: USA; Case Owner: [redacted]; First Received: 5 Jan 2016; Method: Web form; Cal recipient: Migration; Responsible: [redacted].
- Patient Details:** Species: Dog; Breed: Shepherd Dog - Austr; ID name: [redacted]; Patient # 1 of 1; Sex: Female; Repro status: [redacted]; Female phys: [redacted]; Date of birth: [redacted]; Age (from): 3 Year(s); Age (to): [redacted]; Age (text): [redacted]; Weight from: 34.000 to [redacted] Pounds; Approx: [redacted].
- Product Details:** Product: Modified Live Virus, Avirulent Live Culture; Product Role: Suspect product; Product # 1 of 1; Start Date: 19 Oct 2015; End Date: 19 Oct 2015; Ongoing: [redacted]; Product Serial #: [redacted]; Product Lot #: [redacted]; Expiry date: [redacted]; Lot qualifier: [redacted]; Diluent Serial #: [redacted].
- Notes:** Call Notes: [redacted]; Narrative: On October 19th, 2015, my 3 1/2 year old healthy Aussie/Colie mix received intra trak ic at 9:30 a.m., with no other vaccines. At 4:00 that afternoon she became lethargic with vomiting (4 times) and severe diarrhea. She then layed down, had a hard time breathing; Conclusion: [redacted].
- Complaint types:** Verification complete; No more information expected: [redacted].

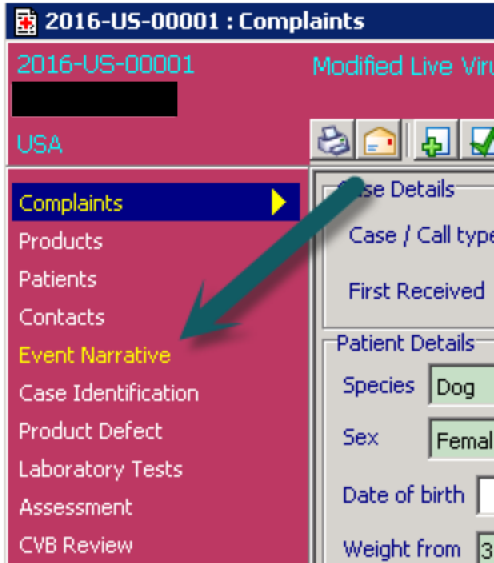
Buttons at the bottom left: Save and exit, Save, Cancel, Help. Status at the bottom: Audit Trail is on, Audit scope is not set.

Review the information in this field as a summary of the case.

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Coding a Case:

To code a case, select the Event Narrative screen from the left menu of the Complaint Screen as shown here:



The Event Narrative Screen will appear as follows:

The screenshot shows the '2016-US-00001 : Event Narrative' screen. The left sidebar menu is expanded, and 'Event Narrative' is highlighted. The main content area displays the event narrative for '2016-US-00001' with a 'Modified Live Virus, Avirulent Live Culture' product. The event occurred on October 19th, 2015, involving a 3 1/2 year old healthy Aussie/Collie mix. The narrative describes the animal's symptoms (lethargy, vomiting, diarrhea, breathing difficulties) and the subsequent treatment (intratracheal injection) and euthanasia. The screen includes fields for Clinical Signs, Narrative, Duration of event (Start date, End date, Duration), and Reaction Type. The 'Was the adverse reaction treated?' field is set to 'Yes'. The 'Outcome of reaction to date' is 'Euthanasia'. The 'When reaction appeared, treatment...' field is empty. The 'Reaction Type' field is empty. The 'Audit Trail is on' and 'Audit scope is not set' are displayed at the bottom.

Preferred Term	System Organ Class	Low-level term	High Level Term
Anaphylaxis	Immune system disorders	Anaphylactic-type r	Allergic condons

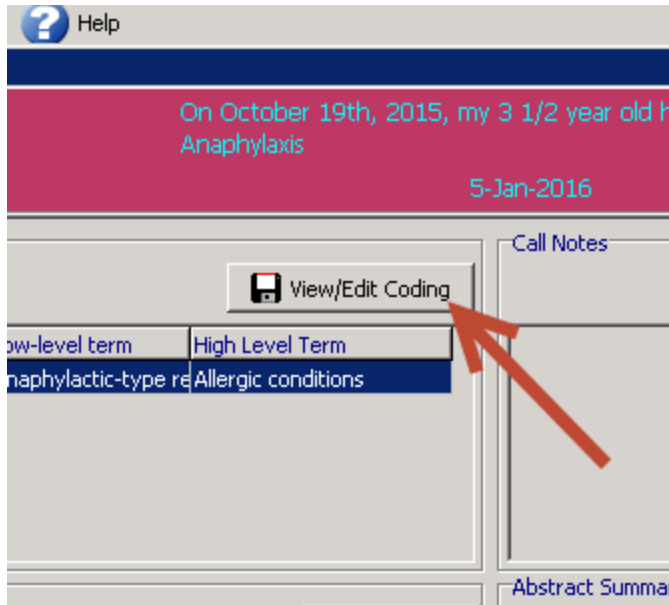
Duration of event:
Start date: 19 Oct 2015
End date: [] [] [] [] [] []
Duration: 2 Days
Duration (text): []

Was the adverse reaction treated?
 Yes No Unknown

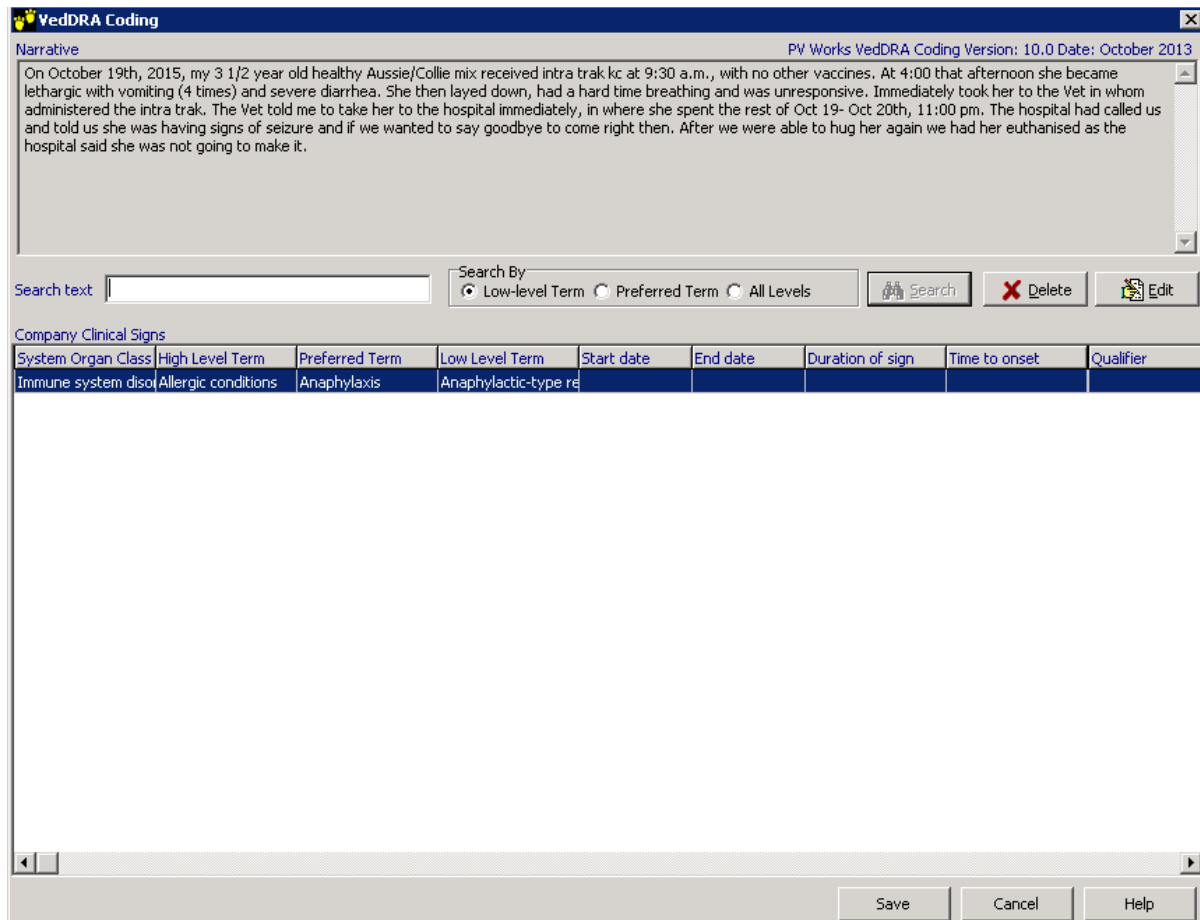
Outcome of reaction to date: Euthanasia
Reaction Type: []
When reaction appeared, treatment...: []
...and the reaction: []

Reviewing, Coding and Assessing Adverse Event Reports in PV-Works

Select the View/Edit Coding icon as shown:



The VedDRA Coding screen will appear as this:



Reviewing, Coding and Assessing Adverse Event Reports in PV-Works

After you select the proper Low-level term, save the code by selecting the Save icon. An audit trail field will be displayed after saving the first VedDRA code as shown below. From the pull-down menu, select “New Information Available” and then save. Proceed to the next clinical sign in the narrative until all are coded.

Audit Trail

Reason for Change
New Information Available

Adding Audit Trail

Old Lethargy (see also Central nervous system depression in 'Ne...
New Lethargy (see also Central nervous system depression in 'Ne...

Save Help

When the list of codes are complete for the case, save the VedDRA coding screen:

2016-US-00001 : Event Narrative

2016-US-00001 Modified Live Virus, Avirulent Live Culture On October 19th, 2015, my 3 1/2 year old healthy Aussie/Collie mix received int Anaphylaxis

USA

Complaints

Products

Patients

Contacts

Event Narrative

Case Identificat

Product Defect

Laboratory Test

Assessment

CVS Review

Call History

Document Mana

Follow-up Mana

VedDRA Coding PV Works VedDRA Coding Version: 10.0 Date: October 2013

Narrative On October 19th, 2015, my 3 1/2 year old healthy Aussie/Collie mix received intra trak cc at 9:30 a.m., with no other vaccines. At 4:00 that afternoon she became lethargic with vomiting (4 times) and severe diarrhea. She then layed down, had a hard time breathing and was unresponsive. Immediately took her to the Vet in whom administered the intra trak. The Vet told me to take her to the hospital immediately, in where she spent the rest of Oct 19- Oct 20th, 11:00 pm. The hospital had called us and told us she was having signs of seizure and if we wanted to say goodbye to come right then. After we were able to hug her again we had her euthanised as the hospital said she was not going to make it.

Search text: EUTHANASIA

Search By: Low-level Term Preferred Term All Levels

Search Delete Edit

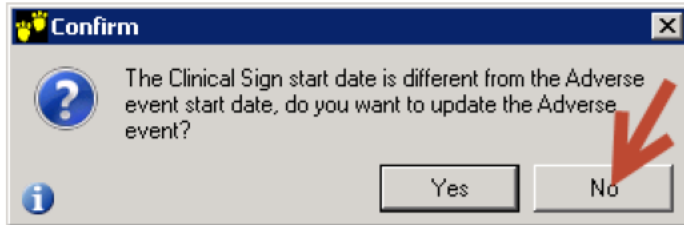
System	Organ	Class	High Level Term	Preferred Term	Low Level Term	Start date	End date	Duration of sign	Time to onset	Qualifier
Immune system diso		Allergic conditions	Anaphylaxis	Anaphylactic-type re						
Systemic disorders	General signs or sym	Lethargy	Lethargy (see also C							
Digestive tract dsor	Stomach disorders	Emesis	Vomiting							
Digestive tract dsor	Other digestive tract	Diarrhoea	Diarrhoea							
Respiratory tract dis	Bronchial and lung d	Dyspnoea	Dyspnoea							
Neurological disorder	Impaired conscious	Loss of consciousness	Unresponsive to stim							
Neurological disorder	Convulsions and epil	Convulsion	Seizure NOS							
Systemic disorders	Death	Death	Death by euthanasia							

Save and Save Cancel Help

Audit Trail is on Audit scope is not set

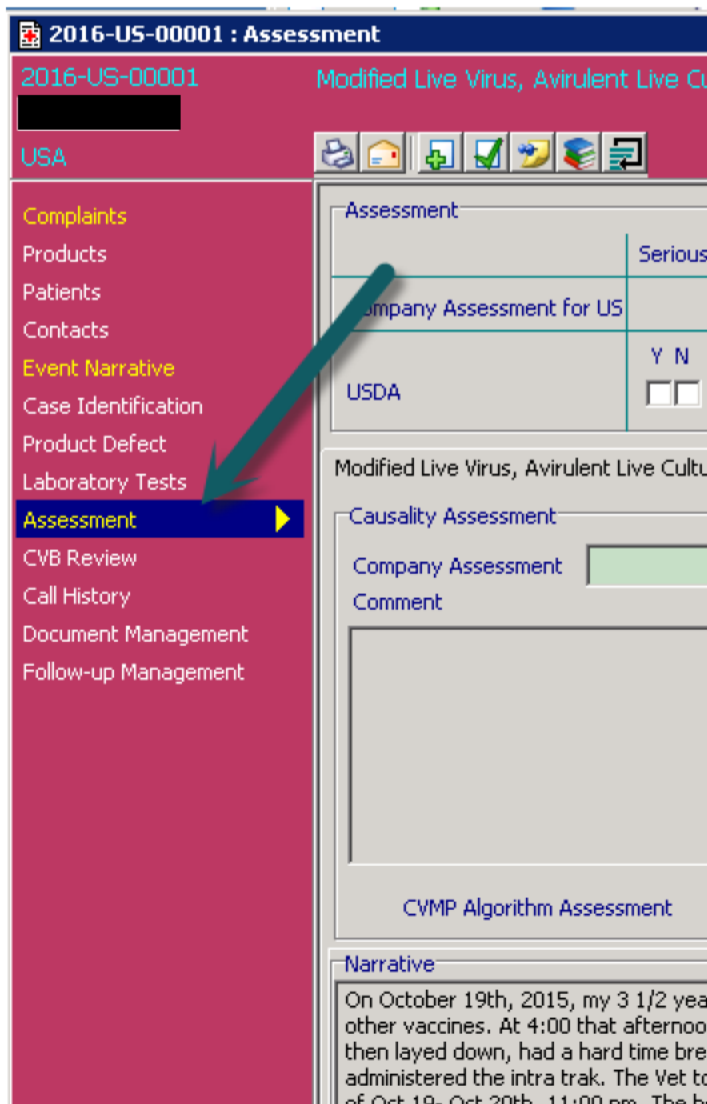
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If the following message appears, select no:



Assessing a case

Select the Assessment link on the left hand side of the screen as follows:



Reviewing, Coding and Assessing Adverse Event Reports in PV-Works

Assign the time to onset and the USDA causality assessment to each clinical sign for each product as shown below:

Narrative
 On October 19th, 2015, my 3 1/2 year old healthy Aussie/Collie mix received intra trak kc at 9:30 a.m., with no other vaccines. At 4:00 that afternoon she became lethargic with vomiting (4 times) and severe diarrhea. She then layed down, had a hard time breathing and was unresponsive. Immediately took her to the Vet in whom administered the intra trak. The Vet told me to take her to the hospital immediately, in where she spent the rest of Oct 19- Oct 20th, 11:00 pm. The hospital had called us and told us she was having signs of seizure and if we wanted to say goodbye to come right then. After we were able to hug her again we had her euthanised as the hospital said she was not going to make it.

Clinical Signs

System Organ Class	High Level Term	Preferred Term	Low-level term	Time to onset	Causality
Immune system	Allergic condition	Anaphylaxis	Anaphylactic-type rea	6 Hours	A - Probable
Systemic disorder	General signs or	Lethargy	Lethargy (see also Cer	6 Hours	A - Probable
Digestive tract c	Stomach disorder	Emesis	Vomiting	6 Hours	A - Probable
Digestive tract c	Other digestive t	Diarrhoea	Diarrhoea	6 Hours	A - Probable
Respiratory tract	Bronchial and lun	Dyspnoea	Dyspnoea	6 Hours	A - Probable

Time to onset first dose: 6 Hours
 USDA Causality: A - Probable

Complete the CVB review by selecting the CVB Review on the left side of the screen. Using the pull down menu of the Final Actions/Review outcome field, select Reviewed as complete and select No More Information Expected toggle. Select Save and exit.

Case Identification
 Product Defect
 Laboratory Tests
 Assessment
CVB Review
 Call History
 Document Management
 Follow-up Management

USDA Administration
 Document type / MA number: USDA Report, 9999
 Submission type: Annual Report, DUMMY
 Package type: ADE, 1
 Purpose type: Voluntary report entered from the field
 Reportability: Voluntary report entered fr

Triage / Review
 History
 Report received: 5-Jan-2016
 Registered on: 5-Jan-2016
 Database entry on: 5-Jan-2016
 Assigned reviewer: Migration

Initial: AWAITING REVIEW
 Final Actions / Review outcome: Reviewed as complete
 No More Information Expected:
 Close case after review:

Document id	Submission id	Package id	Received on	Report	Status
U9999	ADUMMY	A1	5-Jan-2016	Initial	Case entered into database

Save and exit
 Save
 Cancel
 Help